HIT Policy Committee Final Transcript April 4, 2012

Presentation

Mary Jo Deering - Office of the National Coordinator

Thank you very much, operator. Good morning, everyone. This is Mary Jo Deering in the Office of the National Coordinator for Health IT. This is a meeting of the HIT Policy Committee. It is a public meeting and there will be an opportunity for public comment at the end. I'll ask all the members to identify themselves when they're speaking because we will make a transcript of this. I'll begin by taking the roll. Farzad Mostashari?

Farzad Mostashari – National Coordinator for Health Information Technology

Mary Jo Deering - Office of the National Coordinator

Paul Tang?

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Here.

Mary Jo Deering - Office of the National Coordinator

Dr. Agarwal? I think Dr. Terry Cullen is sitting in for her. Terry's here but she may have stepped out.

W

(Inaudible.)

Mary Jo Deering - Office of the National Coordinator

David Bates? Christine Bechtel? She stepped out. Neil Calman?

Neil Calman - Institute for Family Health - President & Cofounder

Here.

Mary Jo Deering - Office of the National Coordinator

Richard Chapman?

<u>Larry Wolf – Kindred Healthcare – Senior Consulting Architect</u>

Larry Wolf for Rick Chapman.

Mary Jo Deering - Office of the National Coordinator

Patrick Conway? Art Davidson?

Art Davidson – Public Health Informatics at Denver Public Health – Director

Here.

Mary Jo Deering - Office of the National Coordinator

Connie Delaney?

<u>Connie Delaney – University of Minnesota School of Nursing – Dean</u>

Here.

Mary Jo Deering - Office of the National Coordinator

Paul Egerman?

Paul Egerman - Software Entrepreneur

Here.

Mary Jo Deering - Office of the National Coordinator

Judy Faulkner?

Judy Faulkner – Epic Systems – Founder

Here.

Mary Jo Deering - Office of the National Coordinator

Thomas Greig? Gayle Harrell?

Gayle Harrell – Florida – House of Representatives

Here.

Mary Jo Deering - Office of the National Coordinator

Charles Kennedy? David Lansky?

David Lansky - Pacific Business Group on Health - President & CEO

Here.

Mary Jo Deering - Office of the National Coordinator

Deven McGraw? Frank Nemec? Marc Probst?

<u>Marc Probst – Intermountain Healthcare – CIO</u>

Here.

Mary Jo Deering - Office of the National Coordinator

Joshua Sharfstein?

Josh Sharfstein - Maryland Department of Health and Mental Hygiene - Secretary

Here.

Mary Jo Deering - Office of the National Coordinator

Latanya Sweeney? Rob Tagalicod? Scott White?

<u>Scott White – 1199 SEIU – Assistant Director & Technology Project Director</u>

Here.

Mary Jo Deering - Office of the National Coordinator

Thank you. Christine Bechtel, would you like to – here, thank you. Thank you, Farzad.

M

Judy's on the call, Judy Murphy?

Mary Jo Deering - Office of the National Coordinator

Judy Murphy, are you on the phone?

M

She was just on, Mary Jo.

Mary Jo Deering - Office of the National Coordinator

That's what I thought.

M

(Inaudible.)

<u>Farzad Mostashari – National Coordinator for Health Information Technology</u>

I was supposed to be on vacation and Judy had agreed to pinch-hit and make some remarks, so I actually don't have anything prepared to say, other than it looks like an important agenda and I hope I made the right decision by not taking a vacation day today.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Okay, well we'll welcome Farzad anyway to listen in and participate in the discussion. We do have a very full agenda, and it really concentrates on reviewing the NPRM and providing a response. All of the groups will be presenting some initial work for feedback from the full committee and then go into making final recommendations over the next month.

I want to welcome everyone to this meeting. I think basically each of the workgroups is going to present some of their initial ... with the Meaningful Use Workgroup. There are some of the NPRM provisions that apply most specifically to Information Exchange, some for Privacy and Security, the Quality Measurements Workgroup, and Certification Adoption, so pretty much all of the workgroups are engaged in looking at the proposed rule and providing feedback, which the Office of the National Coordinator and CMS really appreciate. Before we proceed we want to ask for any comments on the minutes, any corrections. I think were some misattributions, which I'll pass on to Mary Jo later. Any other comments on the minutes? If not, I'll entertain a motion to approve them.

M

So moved.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Any seconds? Any discussion? All in favor?

ΑII

Aye.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Any opposed or abstained? Thank you. Well, we'll get right into it and we'll start out with the Meaningful Use Workgroup draft recommendations, and George and I will present that.

Okay, so what we're going to present are some of the initial recommendations that are thoughts for input from this overall committee. First, I want to begin with the membership, and this has been a steadfast group that's worked with us over the past, what, about three years, beginning with Stage 1, the framework for Meaningful Use, and now we're working on Stage 3, though we've taken a pause to comment on the NPRM. We'll present our initial response for your feedback. There were also some comments and questions embedded in the NPRM and we've taken a look at a selected number of those questions and provided some response for your feedback as well, and we'll conclude of course with the question and answer and discussion.

What we've been doing since the NPRM was released is looking at those and having a series of calls, including a face-to-face. We've come up with some initial thoughts on those and we're presenting those to you today. We're getting your feedback and we'll take that and reconcile that with some of the comments that we had proposed and re-work that and bring it back to this group next month, on May the 2^{nd} . The goal then is to have a final recommendation that we can present and submit by the due date of May 7^{th} .

So to get right to it and the first one in category one, which is "Improve Quality, Safety, Efficiency and Reduce Healthcare Disparities," one of the top objectives is really to look at CPOE. As you know, that's probably, in addition to having all of the information that you need at your fingertips at the point you're making decisions, at the time you're formulating your orders we want to have that information and the

additional benefit of clinical decision support to be helping to shape those orders, so CPOE is a critical functional piece of an EHR. We began in Stage1, as you know, we originally proposed having CPOE accompanying all order types, got some pushback and started out with medications at 30% because there was already electronic prescribing, another incentive program, in place. With Stage 2 this committee proposed that we add lab and radiology and make the threshold 60% except for radiology. What was in the NPRM was to include lab and radiology, make it 60% in total, and also to change the denominator. We looked at a number of those attributes of the proposed rule and have the following comments. One is, the new denominator was all orders and then the numerator was the orders entered by CPOE, and so the question was should all orders include those that are not entered into the system, i.e. paper orders?

If it's easy to get paper orders, then that's a reasonable numerator and denominator. If it isn't, then what we had counter-proposed is to take a look at make it results based, so in other words, for each of those order types, meds, labs, and radiology, you have a set of results that are in the EHR and those we were proposing to be the denominator, so that could be easily calculated. The numerator then would be the orders being entered via CPOE that would match up to those results. Let me try to explain it again. Lab test results appear in the EHR, and that's a result of some order, so we were proposing that as an automatic denominator, a denominator that you can easily access, then the numerator would be the orders that are entered through CPOE. So that was our counter-proposal in terms of an easy to calculate way of getting at the use of CPOE.

The other comment we had was about 60%, our understanding of the rule was that 60% was overall, so if you took all the orders for meds, labs, and radiology, then if you had 60% that would qualify. And our concern there was that you could actually, using the math, escape one of those three categories by having a higher than 60% in the other categories, so our suggestion was to go back to 60% of each of the order types.

A final comment has to do with the question that was posed would scribes be okay, in other words, currently in Stage 1, and what we proposed for Stage 2 was that the order had to be entered by a licensed professional. Our thinking was because this is where ordering is a contact sport and you really want to have the system information and the system decision support influence the orders that are written at the time they're written rather than trying to chase after and re-work an order that wasn't necessarily appropriate. That's why the group still feels that a licensed professional, so that's a professional and a legal responsibility of that individual, was important as part of the requirement, so we'll comment on that later in response to another question that was proposed in the NPRM. Essentially, it's what counts and who counts. We thought that we would use the results of each of these order types as the denominator, the entry by CPOE as the numerator, and it be a licensed professional.

The next row talks about drug-drug interaction and drug allergy, and we agree with consolidating that with clinical decision support. We further expanded on our concern about drug-drug interaction, and currently one of the reasons it's gotten our special attention is because of the high rate of false positives. We do know that if you do pay attention to specific drug-drug interactions and hone in on those, like has been done at Brigham and Women's Hospital, that you can switch the false positives and have a high true positive and really influence results. And for that reason one of the caveats we entered is that providers should be able to provide the drug-drug interaction rules to achieve a much higher true positive rate.

The next part has to do with electronic prescriptions. We're going to defer, for the final recommendations, to the Information Exchange Workgroup. We had proposed raising it from a 40% threshold to a 50% threshold, the NPRM called for 65%, and we're a little bit concerned there because in some areas of the country or with patient preferences they may not know what pharmacy they want to go to and there's a reason that some would choose to have a paper prescription, particularly for the initial one. So for that reason we were concerned that 65% might be a bit high, but we'll defer the final recommendation to the IE Workgroup.

Next has to deal with demographics, and I think we agreed with the proposed rule going from 50% to 80%. Currently the NPRM talks about following the 1997 OMB categories. Our thought was to get more

granular over time. We're aware that CDC, the Office of Minority Health in the CDC used a more granular demographic as standards for their surveys, and those are mapped up to the 1997 OMB standards. Our recommendation is to move into a more granular capture of this demographic information, and so we've added that as our recommendation.

Maintaining up to date problem list meds and med allergies, that's close to our heart, and the NPRM suggested that they be consolidated as fields as part of the Summary of Care document. The workgroup felt very strongly that these are important separate objectives for the following reasons. One is, right now the problem meds and med allergy lists are not necessarily up to date as they exist in the systems, and it has been useful to have the meaningful use program push all the providers to make them more complete and make them more accurate. The workgroup had been looking towards future stages to add additional functionality that would support the maintenance of up to date and accurate lists. So, for example, there are some diagnoses, let's say diabetes, where you can use other information in the record, such as the A1c or the glucose, and propose, hey, if this is missing, if diabetes is missing on the problem list that that can be brought to the provider's attention.

There are other ways to use other information in the EHR to help prompt and stimulate re-thinking of the problem list, for example, and cause it to be more up to date, and that's the kind of direction we wanted to go because of the high leverage, the high value of these lists and if we lost a focus on those particular, very important lists then we think that we might undermine some of the importance of it. One is the importance of maintaining these lists in a very prominent way, that we wanted to get more rigorous capabilities in the EHR to facilitate that maintenance, and finally, that if it were buried in a document like the Summary of Care document, which could actually be produced automatically, it might actually be even out of sight of the provider. So it's for those reasons we were in favor of maintaining those objectives as separate ones.

Going on to clinical decision support, which as we all recognize is one of the important attributes of an electronic health record system, Stage 1 had one CDS rule; Stage 2 we had proposed broadening the description of CDS without being prescriptive in terms of what qualifies as a decision support rule or not. We're in agreement with the proposed rule saying that it be a number, five CDS interventions, and that it be linked to CQMs. We noticed that in the preamble there was a description of some of the attributes that we had listed, but to our knowledge it didn't appear in the certification criteria. And so some of the attributes of CDS we thought were important enough that we'd re-list them and enumerate them and hopefully would suggest that they become part of the certification criteria.

The other thing is we certainly agree with drug-drug interaction and drug allergy being part of CDS, but in addition to the five interventions we would propose that an additional one like DDI be decision support functionality that addresses efficiency, that's not one of the prime objectives for HITECH. And a couple of the areas that we suggested were the overuse of high cost imaging or the use of generic medications would be areas where we could be productive, and there's been evidence that shows decision support applied to those two domains can be very useful from both an appropriateness point of view and from an efficiency cost point of view.

The next one is the advanced directive, another thing that strikes close to the heart of the Meaningful Use Workgroup members. We had proposed that we move towards not only indicating that an advanced directive be indicated as being available or not available, but if available that we have a point or two where you can access it. We understand from the NPRM that there are state laws that can complicate the matter and we agreed to investigate that further, perhaps even in the hearing. But because we felt so strongly about the importance of choice in respecting the individual's desires at that stage in their life, we did recommend that we proceed with moving from a menu option to a core objective. In the NPRM it still was listed as a menu objective. And for the same reason we thought it was advisable to go for EPs to move it to a menu requirement on the way to core in Stage 3, at least that's how we would recommend, and we backed off on the point or two where it is in acknowledgement of the state differences.

With respect to the list of patients, the only difference between our recommendation and the NPRM was we had suggested multiple specific conditions, meaning we're just trying to up the ante in terms of the

flexibility of EHRs to report based on multiple variables rather than just one. Sending reminders to patients originally in Stage 1 was 20% of those 65 or older or 5 or younger and we had broadened that to 10% of all active patients. The NPRM says the same thing. The only caveat we threw in was that seems very reasonable for primary care and we can imagine some specialists, and particularly surgeons, who might not require follow up or health maintenance kinds of reminders, so that may be a consideration with respect to the 10% threshold.

A new requirement that was introduced in the NPRM has to do with imaging, and the workgroup is very receptive to that and very supportive of that. Our only concern was whether 40% was high at this point in time, especially in areas where they may have more limited suppliers of imaging results. So our suggestion was instead of 40%, to make it a 10% threshold and also have an exclusion where someone is practicing in an area where the imaging centers just don't have that, aren't able to provide that information back to the provider.

The second part was in the NPRM there was a potential measure of saying that 10% of the images would be actually transmitted back to the provider, and the workgroup, of course, is in agreement with the spirit of that potential measure, but again for similar reasons think that Stage 2 may be too early to expect 10% of all the orders to be coming back electronically.

The next menu item is a new objective for family health, and again, the workgroup is very much in support of the spirit of this objective but is not aware of standards that already exist for family health, although many EHR systems capture in structured form their structure that is specific to an individual vendor or even to an individual provider. That's one concern.

The second concern has to do with the definition of family history. It can be very simple or it can be very comprehensive and do we understand how much of the time should be spent on capturing a comprehensive family history on every visit. The other consideration is that we're moving towards family history to genomic history so that we actually know the impact of genes on an individual's health.

Next has to do with progress notes, we visit it a couple of times in Stage 1. We did recommend it in Stage 2. And in the NPRM it says that one of the reasons not to have it as an objective is because the current EHRs have them. It was a feeling of the workgroup that, and particularly with hospitals, not all of the EHRs do have clinical documentation as a primary function or is implemented as such, and because of our belief that progress notes is an essential part of information about an individual and participates in the decision making, that we wanted to make sure that all of the EHRs have the capability and that that capability is implemented.

Moving on to engage patients and families, George, we're going to go through all the categories and then come back and get your feedback on each one, category by category.

George Hripcsak - Dept. of Biomedical Informatics Columbia University - Chair

Thanks, Paul. Thank you for the opportunity to present today. Remember, engage patients and families, we suggested restructuring it, and that was adopted and we agree with that. One thing that was asked in the NPRM was timeliness, how should we do this. Remember, we had originally suggested 24 hours for the summary and then 4 calendar days if new results came in. The NPRM came back with 24 hours for the summary, this is for eligible professionals we're talking now, with 4 business days, which is actually a longer period of time. And so we deliberated and said, can we come up with one consistent measure? For example, if a lab test comes in the day before your visit, do you have three more days after your visit to send it, or do you have to send it in by the next day and so on? Can we be consistent across all these measures? And we felt that perhaps we could move to 2 business days for everything. That's somewhat consistent with our original 4 calendar day, a weekend plus 2 business days would be 4, that's kind of where we came up with the number. We see this as an upper limit. Frankly, these data should be available for patients essentially instantaneously, for the most part, so whether it's 24 hours or 2 business days we think that the information should be immediately available, just as an outer limit, but allows us to have a consistent measure across all our objectives for eligible professionals. So that was one suggestion.

Second, we had a long discussion, actually Paul and I read 80 pages of transcript yesterday, to determine the details of this. We had suggested, remember our original proposal was that for eligible professionals that patients could actually, in EH 10% of patients would have to log on to the system in order to qualify. What we determined, one thing was that our original suggestion said 10% had to log on ever, the NPRM says 10% have to log in per reporting period, which is a stricter standard and perhaps a little bit harder to do, as you know, patients are much more likely to log in when they first get it. We had a prolonged discussion, not specifically with that issue, but in general what's the right threshold, and we ended up disagreement. We didn't actually vote on it in the transmittal, but we just shifted topics after that. So I'll just say now we need to do further discussion and decide what to recommend, and we welcome input.

For clinical summaries, again, this goes back to the 2 business days. For secure messaging, now originally we had recommended at least 25 messages because we had been even more concerned about secure messaging being able to achieve a certain percentage. The NPRM suggested that you had to achieve secure messaging for 10%. We felt that was high and we came up with several suggestions for alternative percentiles, and we decided to, yes, keep it with percentiles and we came up with a metric, well, if 50% of patients have to have portal access and 10% of those use secure messaging maybe 5% is a reasonable measure. So we did vote on that and the majority said yes to 5% it was mixed, though, some wanting more than 5% and some wanting less than 5%, but that is what we suggested at this point in time.

Recording preferences for communication, which was eliminated from the NPRM as an objective, we're suggesting that it be included. Now, we recognize that it would be nice to stick to 20 objectives and you have to get rid of something, you have to prioritize, nevertheless we felt that capturing a patient's preferred communication method is needed for the system in order to use the system to pick what medium will be used for future non-urgent communication. And further, we thought it was important to distinguish among multiple message types how did you want that message coming back to you. So we are, in fact, suggesting that be included as an objective.

Under care coordination, for the test of Health Information Exchange we agree with the removal of that as an objective, and that we had actually suggested that originally. The NPRM asked for advice on what to do about Stage 1, and in our deliberations we had come up with using option 4, which is, in effect, doing the Summary of Care record, which is the use case for HIE, a little bit earlier, doing that at the end of Stage 1, but we recognize that the Information Exchange Workgroup came up with a different recommendation and we learned of that, I guess, on Monday, for option one and we believe that we should defer to the Information Exchange Workgroup.

For medication reconciliation, first, to note that the certification criteria should support the reconciliation process, that is, there are a number of things that need to be done for successful reconciliation, comparing multiple medication lists and resolving differences among medications, so just pointing out that this policy objective should trigger that on the certification side. We also note that in order to support the measure the provider needs to capture the fact that a transition has occurred and as far as we can tell the detection of a recurrence of a transition has to be captured manually, and so we recommended that the threshold remained at 50% to give more latitude. In other words, we don't want to create too strong an incentive to not report transitions. In other words, we want an accurate reporting of transitions and have a reasonable percentage of how many you have to have fulfilled this measure on, rather than create incentives not to report transitions for which you're not going to do a reconciliation.

For summary of care, first of all, for the care plan section originally we had suggested goals and instructions as being a care plan, the part that can be coded, and in further discussion recently we felt that perhaps we could include two more fields; one initially, which is the reason for the referral or transition specifically, and then after the referral the results of that referral, that is, the recommendations to come back, so just further defining what constitutes a care plan. Again, we note that to support the measure the provider needs to capture the fact that a transition's about to occur. We do agree, now in the NPRM it suggested two things. One is, for this to count as a transition toward the meaningful use measure that it had to cross organizational barriers and that it had to go to a different vendor system. So

we agree with the requirement that it has to cross organizational barriers. We agree with the spirit of the second half, that it should be between different vendor systems, we understand the motivation for that, that is, you don't want to just promote vendors locking customers in. However, we were a little bit afraid that it may cause unintended consequences. For example, in some geographic regions a few vendors, or one vendor may have a dominant market share and we don't want to promote the practice of coming up with safe transitions to satisfy the objective. So therefore, we don't support the second one, that is, that it has to be a different vendor. Then for these two objectives we agree with the incorporation into the other objective.

Population health, two things here; first of all, if it turns out, based on the NPRM and the reporting period that it's too difficult to do all of these five objectives, that is, the three original and the two new registry ones, that our highest priority is immunization. So typically a statement that if you need to prioritize, in other words, let's say you make one of them core and the rest of them menu, then this is the one that we feel should be core. Secondly, we need clarification on in accordance with applicable law, actually specifically on except where prohibited. So originally Stage 1 said in accordance with applicable law and practice, which was perhaps seen by some as too loose, in other words, if it wasn't in the law that you had to report it and if it wasn't common practice, remember we're trying to change practice, if it wasn't previously common practice to do it then maybe you could be exempt from this thing. So we believe that what was added was "except where prohibited" to make it stronger. In other words, unless it's restricted from doing it, you have to put it forward. And we just raised the question of if the health department receiving it refuses it or cannot accept it, then does the meaningful user not qualify for meaningful use, or are they unable to do this objective, so then what say does the health department have in how EPs respond to this, or EPs and EHs respond to this in their region. Now we realize that in the IE presentation they're going to present the opposite view, which is that perhaps too much latitude has been given to health departments, and that's something that we need to talk about further. But even we are concerned that "except where prohibited" may be too strong.

The same goes for the second and third reporting objectives. We agree with the cancer registry objective, but when we get to the more general objective about all registries we had a couple of questions. We need to consider whether sufficient standards exist to support interfaces between electronic health records and all these various registries. Panelists in our previous hearings expressed concern about the proprietary nature of some of these registries which affects the cost to participate, you have to pay for it, and in some cases they're exclusive, there are contractual restrictions that you cannot send data to another registry once you participate in this one. Then there's the concern that requiring all the HRs to interface to all data and all registries may be too many end-to-end connections, so we certainly need standards. So there may need to be clarification on this one. And then finally on privacy we defer to the Privacy and Security Tiger Team.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

In addition to some of the comments about the functional objectives, the quality measures are going to be dealt with by the Quality Measures Workgroup, there were additional comments elicited in the NPRM, and there were a lot of them, so we focused on just a few key ones but open to other things as the group would request. One has to do with group reporting. We don't really have a consensus to report on at this point and we'd like to open it up, but let me share with you some of the discussion. On the one hand we definitely would like to support addressing the high priority conditions. Second, we would like to move towards team-based care rather than focusing on one individual responsible just for that patient, and we want to align with all the programs that CMS has in that direction. The intention is we want to make sure that we fulfill the HITECH objectives of having all providers using these tools to measure and improve care.

Then the other, we want to move towards the group responsibility, the team responsibility for individuals and populations; so two aspects, one is the functional requirement, and should each individual EP be responsible for using and making meaningful use of an EHR. The feeling of the group at this point, open to your comments, is that individuals should be responsible for making meaningful use of the tool; the second point having to do with quality measures is in a sense the outcome of use of that tool, meaningful use of that tool, it's pretty hard to figure out how to both satisfy the objectives of measuring people as a

team or as a group and at the same time not letting individual providers really opt out of that group participation. So that's the intention that we had, and my understanding is the Quality Measures Workgroup had that same intention. So we'd really appreciate the feedback and input from this wider group. The goal is really to have performance be team-based but yet not have anyone opt out of the use of both the functionality and the data that comes from it via the quality measures.

The second piece has to do with EHR safety. As you know, this group actually made a recommendation to ONC to have an independent study of the issue of safety of EHRs and the IOM was commissioned to produce a report. They've done that and it's been presented back to ONC. The question here, and in the certification rule there are a number of ways that they address the recommendations including describing or documenting a quality management process, not prescribing a specific one, but documenting what you do. And the second area has to do with user centered design, again, not specifying a specific approach to user-centered designs but documenting what you do. And finally, the use of common formats to report back any patient safety concerns. What the group decided to do is to ask whether HITPC should take a broader view of the IOM recommendations related to patient safety, effects of using EHRs and then we could form a Tiger Team dedicated to respond to that and reporting back some feedback to ONC.

With respect to the whole approach of menu versus core, there was an NPRM solicitation of feedback on that approach. Initially in Stage 1 there was a menu and core and it was promised that all the menu would become core, and largely that's true, but there's a continuation of the menu approach in Stage 2 and that's what the comment was requested. The workgroup supports this approach for a number of reasons. One, it does provide flexibility in an otherwise all-or-nothing qualification rule, so that's a good approach. The second is that it's a good way of providing strong signals because you can create a menu requirement that later becomes core and so the vendors and the healthcare organizations have a very strong signal in terms of what to prepare for in future stages. In general, we support this continued use of menu and core.

Next has to do with licensed professional, we already touched on this, and the specific ask was what about use of scribes. It's our belief that we really want the EP to be able to act on automated decision support and be accountable for the orders, so in our opinion it requires a licensed professional to actually do the order entry in order to meet those attributes.

Finally, another question had to do with OTC medications and whether they should be included in the denominator. The group felt that OTC medications are very important on the med list because it's important in terms of the way it affects the human body and also is important as part of drug-drug interaction. So we recommend that certification criteria include the requirement that EHRs be able to capture OTC medications without, in this case, transmitting to the pharmacy. Yet because OTCs can span a number of chemical ingredients we agree with the NPRM that it not be included in the denominator.

A question about additional demographics and disability status, while, again, it's important to signal the need for this to appear in the record, it's our belief that the data standards do not yet exist for, for example, different kinds of disability status, for gender identity, and for sexual orientation. So it's an important part of an individual's health, and we don't, at this point, feel that we have the data center standards to make this a requirement.

Summary of Care record, now it looks like we've, in a sense, as I reviewed this for this presentation we provided an answer but it wasn't an answer to the question that was proposed, but at least let me provide you with the answer that we discussed. There were a number of fields that were enumerated to be part of a Summary of Care document. Similarly, there were a number of fields enumerated for the clinical summary for the patient. The Summary of Care document is intended for use by providers. The clinical summary is intended for use for the patient. And we wanted to make sure that even if the information content was similar in both documents, that the way it is rendered by the EHRs may be very different. So you use the same data standards to communicate the information from one system to another, but there should be functionality that allows the healthcare provider organization to translate some of the medicalese into patient friendly information, because that's how it's going to be most useful to the patient. One of

the caveats there, one of the fields is labeled "Relevant Past Diagnosis," and we couldn't figure out how the machine would know that by itself and so that automatically means it would require human intervention, and that could be difficult to implement, so additional specification in terms of how you define relevant past diagnosis would be appreciated.

Another question was what about the notion of including functional and cognitive limitations? We looked at this and we questioned why would this stand out to be different from any other health condition where you would include that, if applicable, on the problem list, so we didn't find that to be a stand out or have a standalone requirement.

With respect to public health and syndromic surveillance, this repeats what George said about we find it to be pretty hard for the public health departments to fully implement all three of these and that the highest priority should be with the immunization registries.

We've gone through a lot of material, maybe the way to structure some of the response and discussion is to go category by category, but not item by item. If we can go back to category one, which was the improved quality, safety, efficiency, and reduced healthcare disparities and open it up and ask for your comments and questions. Marc?

Marc Probst - Intermountain Healthcare - CIO

Just a quick question, on the denominator issue on early, the first page, is it truly a one-to-one relationship between order and results within these systems, or is there a variance? I can think of, on the positive side, there are orders that will not get resulted because they may be terminated or decided by whoever's receiving that order, that it's not a necessary order. I'm wondering on the other side if it's really one-to-one.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

I think you have a good point. There are orders that are never carried out and it may be not to the "fault" of the provider, and clearly there are orders that get transmitted and results appear, maybe ordered outside of the EHR and results appear. That's why it's not 100% that CPOE, but we wanted to find some countable number that doesn't require manual intervention, and so our best thought on that was to go get all the results, it means there was an order somewhere, and to make sure that we have a sufficient number that were covered by CPOE. That's one of the reasons for not going to 80%, for example, or 100% for sure, so 60% it seemed like —

George Hripcsak - Dept. of Biomedical Informatics Columbia University - Chair

But as stated over there, remember, what we're saying is if it's countable. There's a statement in the NPRM that the paper orders should be countable and this is easy to do. If that's the determination then we're not suggesting this. We're saying that if you can't do paper orders here's our suggestion as an alternative, but we're not stating that we have to move to this, just let me emphasize that.

Marc Probst - Intermountain Healthcare - CIO

Yes, and it's going to just reaffirm my ignorance, but I'm wondering, are there orders that create multiple results?

M

Yes.

Marc Probst - Intermountain Healthcare - CIO

So you're not going to have a one-to-one relationship.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Farzad?

Farzad Mostashari - National Coordinator for Health Information Technology

I think it was that point, and also there are orders that are never resulting, unfortunately, so where you don't close that loop ... been discussion of an under count in that sense as well, but I think it's helpful to make sure that it's clearly understood that we hope that this is, or the workgroup is saying we hope that this is not going to be necessary, these all will have their problems, medications on the med list. And particularly I think, I don't know if there was discussion of this, if you're not talking about group reporting, if you're talking about a practice with ten providers and trying to figure out for each of those providers which ones of the medications on the med list are ones that should count towards them and how many orders did they – so it does get complicated. And one of the values that we're really trying to forward in this iteration is more simplicity and less complexity, less regulatory burden, as I tell Steve Posnack all the time, "Be less clever. " So that was just my comment about being careful that we're not being overly clever.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

So clearly we have the same goals in mind, we're just trying to figure out how to do it in the simplest way possible. I think Terry was next.

Terry Cullen – Director, Health Informatics, Veterans Health Administration

I just want to reiterate this because my concern with labs is obviously panels, and I don't know how they get counted, so obviously if the EHR can ascertain that the order was a panel and now there's 20 results because you're never going to meet even the threshold if that's what happens and you're doing a lot of panel-based labs. My other comment is about the scribes, and I can defer that until later. I just think there are certain situations, and I still work in an emergency room, where depending upon who the scribe is if there are standing orders that are based on your entry into the emergency room you may or may not get an LP reviewing that order, and actually you probably don't want one because you don't want to interfere with the EKG that needs to happen right away.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Let me address the first one, which I think was addressed in the NPRM, is that panels would count as separate tests on either side. I think that deals with that issue.

Terry Cullen, - Director, Health Informatics, Veterans Health Administration

Except it would be one order.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Well, you would just decompose it into all of the orders.

Terry Cullen - Director, Health Informatics, Veterans Health Administration

Okay. I guess my worry is the results all need to be counted granular, so you'll have 20 results in one order, unless you say it's always a 20:1 relationship then –

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

I think what the NPRM said was a panel of 20 orders -

Terry Cullen - Director, Health Informatics, Veterans Health Administration

... will count as 20.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Would count as 20, so that it would match up with the results. With respect to the scribe, and this is an appropriate place to mention this, anything that is legal from a state point of view would count and our understanding is that's why we used the term "likeness" initially and I think that's the way it was used in the final rule. The notion of a scribe would be then an unlicensed person who does not have either the professional or legal liability of being accountable and we don't have a way of matching that one-to-one to the ordering or the authorizing provider. So that was the thinking, I think, the group was concerned about, because so much of the benefit comes from shaping orders.

Terry Cullen - Director, Health Informatics, Veterans Health Administration

And it may be to tease out the definition, so a medical assistant that's not really an LP but in a certain situation is ascribed that power, so what –

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

So the thinking was that if the state allows an MA to order on behalf of someone then that would be okay. But if the state doesn't, then that person would be acting in a scribe position and that wouldn't fulfill at least the intent that the Meaningful Use Workgroup was hoping to achieve. But this is something we need more input on. Larry?

Larry Wolf - Kindred Healthcare - Senior Consulting Architect

I'm not quite sure which of the sections these comments fit in so I'll start in here since scribe is a good entrée into the team. A lot of healthcare is not just a contact sport, it's a team sport, and on the one hand scribe could be sort of an escape clause, "I don't want to deal with that ...ing computer, let the scribe deal with it." But it also could be we have a team working together to figure out a care plan that's coordinated across disciplines and somebody on the team is interacting with the computer and may be describing alerts that come up to the team, and so I think we'd want to encourage that kind of teamwork rather than discourage it.

So I don't know exactly what that means in terms of scribes or not scribes, but I think the general principle that I'm looking for is that we find ways to encourage collaborative care and not force people back into their disciplines and into their silos in order to check off the points for the guys who are getting incentives. I understand, I think, the discussion around how groups ought to be counted or not counted, I think gets to the heart of that problem of if you're being incentivized to work together how do you tease apart the activity of the individuals so that everybody gets credit and at the same time you're not allowing people to just flow through, because the team as a whole is doing a good job. I understand the complexity here. I like Farzad's comment that we shouldn't get too clever, but I think we really, as one of the principles that we should be looking to improve teamwork and collaborative work and that's both within an organization, as we're talking about, and also across organizational boundaries, as we'll get to.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Let me just make one comment on that. So clearly no one, I don't think, in this room is against team care or collaborative care. I think the issue was the "A" in accountable care organization, and one, there's a certain amount of knowledge and expertise and judgment that has to occur when you view things and decide whether to act, and that's how licensing comes about. That sort of thinking has nothing to do with whether other members of the team should participate. I just want to clarify that piece. Farzad, you had a reaction there?

Farzad Mostashari - National Coordinator for Health Information Technology

I think that this issue of EHRs and scribes, one can speculate about to what extent it's about particular implementations of particular systems and whether if you had good implementation of good CPOE then it actually saves time, it's pleasurable to be able to do the order and to be hands-on the computer and so forth, but there are, we're hearing it a lot, about from pretty thoughtful folks about well, maybe it does actually in certain context high throughput, specialty care, and so forth makes sense to have the use of scribes on behalf of the provider. And it would be good if in your comments there's a pretty detailed consideration given to this issue so that we have the best information we can have from the Policy Committee considering, I think, the inevitable comments that we're going to get on both sides of this issue. So some more thinking and writing on this would be much appreciated.

Then a question for you to consider is whether there's an interaction between this recommendation and the later one you make about reinstituting the notes and if the intent here is to make sure that providers actually do touch the record and it's not just push off to somebody else and the provider never looks at the record, where there's interaction there where with the clinical notes at least that is the provider's words. And also whether scribes, I think the inevitable question will then come there well, do I actually have to type this or is it okay if I use voice recognition, is it okay if I use a scribe, so that's the other question.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Good point. Gayle?

Gayle Harrell – Florida – House of Representatives

Thank you. Excuse my voice, between allergies and airplanes and colds I'm squeaking a lot today. But I think the issue of scribes is probably fundamental to where we go on this whole CPOE as well as the progress note issue. And I think it comes down to what is the determination of liability, and you can perhaps, if you look at who is liable for that order and who is liable for that progress note and really look at how that liability ... comes to play, it's really how to address the whole issue of using a scribe. If you use a scribe where does the liability stop? Is that scribe liable, or are you liable? I think that comes down, and as we start to address it we need to really hone in on that. And if the provider is liable, the provider may not be the one touching the keyboard, but the provider has got to have that direct communication eye to eye with whoever that scribe is. So it comes down to whose license is on the line and who's liable as we look at that whole issue, because it's a very complicated issue. And scribes are going to become more and more important, especially in high volume areas. In emergency rooms scribes are very common, and the question becomes who is ordering, who is liable, and what's the communication between the scribe and the ordering professional.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

It was clearly one of the things that we tried to assess, so you're talking about the accountability. The other side is the influence of the actual order itself, and we missed that with –

Gayle Harrell – Florida – House of Representatives

Correct. But that still is there. It has to be there in order for the eligible provider, who is the responsible entity, and that communication has to be very clear between what that screen says versus as the scribe is taking the notes or whatever. So that communication is essential.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO Neil?

Neil Calman - Institute for Family Health - President & Cofounder

Just quickly, first of all, I don't think we're going to know who's entering the orders, so I don't even know how we're going to measure this. So it might be moot, because to some extent what we do know is who has the legal authority to sign or counter-sign the order, but we actually don't know who's typing it in. And I don't think we're really planning some method of enforcement, but I have a wording suggestion, which is I think consistent with what people are saying, is that what we really want is the person who enters the order to be able to act on the decision support or have direct access to the person who can act on the decision support. I think that takes us away from who's actually typing to being able to really be concerned about the interplay between the decision supports that we're concerned with and somebody's ability to act on it. And I think that decision support needs to be at the point where the order's signed off, because that's really what we're talking about. So somebody could enter a group of orders as a way of facilitating a process, but the provider, or the responsible party, or somebody who has direct access to them in the process of signing that off, which actually sends the order to be executed, would be the one receiving the decision support. I think there's some nuance to this. I think this is solvable by basically just putting some clarifying language in terms of what we really want to have happen here.

George Hripcsak - Dept. of Biomedical Informatics Columbia University - Chair

Just to comment on that last statement you made, I think all the ... familiar with the decision support would pop up at the first attempt to enter an order, but at the counter-signature it doesn't really pop up. Now it's possible that systems could be made to do that, but then you have —

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

 \dots and that's what ties it into what Gayle's saying, because I think we're less concerned about who's keyboarding –

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

... than being concerned about the decision making, and it's as it's being sent out or executed that we really need the decision support. I think the combination of those two things basically indicating that it's the person entering it or somebody who has direct access to that, and then combining that with the point of the decision supports needing to be built at the point of execution of the order, really gets us away from the fact that somebody could be entering this stuff as a way of facilitating it and we wouldn't lose anything in relationship to their ability to act on the decision support. I think it would promote the team concept because if they're not licensed they're not able to actually send the order to be executed and so therefore it solves both issues.

George Hripcsak - Dept. of Biomedical Informatics Columbia University - Chair

I think you have to look at specific workflows that actually get implemented and see how things really go, because it's hard from here to say all the good things – obviously if we build a CPOE system to improve the ordering efficiency and quality then we pay a bunch of human beings to circumvent that because that doesn't make much sense, you have to look at specific workflows, and I think there are a lot of cases it works.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Just as you're saying, we don't really care who types in, we want the effect. So I think just looking at it a little more specifically is what's required to come up with something intelligent on how to do the policy.

George Hripcsak - Dept. of Biomedical Informatics Columbia University - Chair

Yes. But I think it's solvable.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Judy, Marc, and Larry?

<u>Judy Faulkner – Epic Systems – Founder</u>

I agree with George that I think workflow is absolutely critical. And when you think of workflow the way they used to do it with paper, okay, here's a list, you went check, check, check, handed it in, that's fast, or you turned to your nurse and said please order whatever that's fast. So CPOE by itself has to be slower on the computer because it was so easy before.

The other thing is if you mention the workflow the physician is just doing CPOE, so the physician is not using the computer for anything else, just going over and doing CPOE, it's a huge burden then. It is so out of the normal workflow of how to work. So CPOE by itself doesn't work well. You have to have CPOE embedded in all the rest of the stuff that the computer is doing, giving the physician value with information that's showing not just here's something you have to do to collect that information. My observation, looking at various EMRs and the scribes that are used, is although we may think of it as a team effort that's not been the observation. My observation, and this is regardless of EMR, is that they say, oh, we're going to have to do an EMR, let's hire scribes. It isn't that it was a team to begin with; they go out and hire them at that time. So although I like the idea of a team working together, I don't think the reality is in this environment that's what happened.

And here's another thought, if you have a department, let's say it's an ED, and that ED has said let's get scribes, so you get scribes, I was thinking that a new physician coming in and joining, coming out of school, residency, is probably so comfortable with the computer and not at all comfortable with a paper environment that it would be easy. So on the one hand you'd think, well, just let it be because they're going to themselves just use a computer. But if they go into an environment where that's not done, then will they lose those skills and not use the computer. So it's kind of interesting. I don't know, I think we're going to have to watch and see what happens. But my gut feel is let it be. As Neil says, it's hard to track and if you look at the organizations they're going to try to do whatever works best and they'll figure it out.

Now, hopefully what works best is the doctor saying I'm in the middle of this anyway with the patient, why should you do it. I'm just going to continue on.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO Marc?

Marc Probst - Intermountain Healthcare - CIO

I think, George, you really did clarify it with the workflow comment. It seems to me a lot of the decision support, maybe even some of the more valuable decision support, doesn't happen at order. It happens on results. It happens where a whole bunch of criteria is brought together to help modify the care. So the key needs to be around workflow. It needs to be having a physician in front of that computer to do multiple things. And actually ordering is just an event and a whole bunch of other things that are happening with that provider, so I think George is exactly right, focusing on workflow is correct.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO David?

<u>David Lansky – Pacific Business Group on Health – President & CEO</u> l quess not.

<u>Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO</u> Use it wisely.

David Lansky - Pacific Business Group on Health - President & CEO

I have not so much a details question, it's a question about the committee discussion. Coming back to the header of this section, quality, safety, efficiency, and disparities, I'm going back two or three years to our early discussions, I think this is a good time as a weigh station in Meaningful Use 1, 2, and 3 to say are we building the capabilities in Stage 2 that will help us achieve those four goals of this section, and I wonder if the committee has or should take a step back, look at it in the aggregate, and say, is this doing enough to drive efficiency and disparities of the two in particular. I think on safety and quality actually there's really a lot of strong enhancements coming through this part of the rule. Efficiency, there's some, but it tends to be what I would think of as administrative efficiency, in other words, we're capturing data in better ways, bringing it into the record in better ways, but we're not actually translating it yet to clinical efficiency in many cases. And I look back at some of the supporting text in the rule, the rationale stuff, and I think we're falling a little short on achieving some of the things to achieve clinical efficiency in terms of reduce duplicate tests and improve selection of medication and some of those things, which we were hinting at with decision support and hinting at with CPOE, but maybe we solve this more through the quality measures than through the functionality.

But I think it's worth a discussion about are we doing all we could and the literature would guide us to do in terms of achieving better efficiency with this platform. And then particularly on disparities, there's actually remarkably little in the rule about disparities. I think the word appears 6 times out of 500 pages, and it's in there only to say you could use this technology to address disparities and maybe there's a place to push a little harder, for example, in the patient list section, which is a natural place, they list four or five ways you can use lists to improve care, one of which is addressing disparities, but there's no real guidance or push to guide people to look at those issues. So I hope as a Policy Committee we'll have some discussion and maybe in our final comments keep raising the visibility of some of those capabilities that may be a little underplayed so far.

<u>Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO</u> Farzad?

Farzad Mostashari - National Coordinator for Health Information Technology

I was going to raise that later when we talk about ... language and the more granular measures that some of the comments I've gotten around Stage 1 has been why are we collecting this? And any time you ask

providers to collect something but it's not being used it seems pointless. And the reason why we're collecting it is to be able to look at disparities, but I think David's comments are good, if we could actually connect the collection of that information to addressing disparities it would at least make it more clear from a communication point of view in terms of why we're doing it.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

You remember in patient lists we had suggested using multiple variables. Perhaps one of the ways to introduce this is one of the variables can be a disparity variable. Gayle and then Neil?

Gayle Harrell - Florida - House of Representatives

I want to go to a different topic, if you don't mind. If you're talking about disparities let him go first, because I want to talk about a different topic.

Neil Calman - Institute for Family Health - President & Cofounder

More on what David was bringing up, I think that this goes back to quality measures and there's an opportunity for us to call out development of, for example, a quality report on something where we know that there's lots of disparities. We know there's lots of disparities, for example, in diabetes and hypertension control rates and access, and whether or not that's relevant to a particular practice will vary from place to place, but I think just calling it out as a very specific piece that would need to be reported by race and ethnicity and primary language would be a real move in the right direction. I think being very specific about one particular report might be useful, not to take away from what I've said previously, which is that certification should allow us the capability of doing that across any report that we do and reporting it out that way. So I think in that area we should call out some increased requirement.

On the issue of efficiency, I actually sent a few people on the train this morning an e-mail because this multi-specialty group is about to make recommendations on 46 different items for which physicians commonly overprescribe some preventive, some diagnostic, some treatment, and I think that gives us an opportunity to go back to Farzad's critique of the other article that came out that basically said how EHRs are going to increase costs. Another way to counter that is to actually build in enough specificity around places where we can use decision support to reduce costs, but rather than demand that decision supports be built in, we do that in a way of building quality measures that look at a number of these overuse areas and develop quality measures to look at use of antibiotics for sore throats and use of diagnostic chest x-rays for a cough, and think of different kinds of ways that some of these 46 recommendations that are coming out and agreed upon by a variety of specialty societies could be built into very specific decision supports that are tied to quality measures that would really show that we can use electronic health records to improve efficiency.

<u>Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO</u> Gavle?

Gayle Harrell – Florida – House of Representatives

I want to go back to the prescribing and the threshold that we're talking about for electronic transmission of prescriptions. There are many communities where this is simply not available. We have a lot of rural sections of this country and we have many inner-city areas where if you go to 65%, and I know you've noted that you feel 65% may be too high, but I think we need to be very cautious in that you're going to set the threshold too high and have people not qualify under that. So I would very strongly state that going back down to our original recommendation at 50% I think would be very significant to go back down to that, because you don't want to have people go through all what they're going through and not qualify. You will kill this whole system. We have one opportunity to be successful here, and I don't want something that is beyond the control of the provider because of where they live and the community to not qualify. So I would urge us to make a very strong statement there.

<u>Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO</u> Terry?

Terry Cullen - Director, Health Informatics, Veterans Health Administration

I think Marc was next.

Marc Probst - Intermountain Healthcare - CIO

Mine's quick and easy. And first, thanks, you guys have done a lot of good work here, so thank you for that. On drug-to-drug interactions, that last line, "Providers should be able to revise DDI rules," I'd like to better understand what that exactly means because there may be times we don't want providers to change DDI rules and our best practice care team has already developed what those requirements are going to be. What do you mean with that specific request?

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

The motivation for that statement is, one, out-of-the-box some studies have shown that providers will overrule essentially 81% of the drug-drug interaction alerts that pop up. Well, it does two things. One, is they don't ... believe them, but it also decreases the value of the decision support, period. So that's just a bad thing. On the other hand, the Brigham and Women's study showed that when they focused on specific high priority, in their minds, drug-drug interactions and showed them only those, they flipped it around and 67% were acted upon. That's where we want to go. So that's the basis for saying the provider group might have to take the responsibility of figuring out what are good DDIs and high priority, and they also have a legal and professional responsibility, but that they have that capability to insert their own DDI rules to provide to those.

George Hripcsak - Dept. of Biomedical Informatics Columbia University - Chair

In effect, Marc, this is a temporary provision until the industry can produce the DDI knowledge base that works. We're saying if we're going to force DDI then we need to make it more specific than the most specific category that these vendors tend to give out.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Yes, so I guess my suggestion would be is we probably need more research around that. We're basing it on a focused study and there may be better practices, and to have that requirement in there might require people to do something that's less advantageous to their organizations or practice.

George Hripcsak - Dept. of Biomedical Informatics Columbia University - Chair

And we're not asking providers to revise it. We want the certification criteria to say it's possible to revise it. That was our goal, possibility.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Without getting into an argument, again, I'm not sure I'd have that requirement there unless we know that that's something that's going to be beneficial, because then when we go to certification we'll ask people in the certification group to put that capability in there when it may not be the best capability or the most important one that we add to the systems. Terry?

Terry Cullen - Director, Health Informatics, Veterans Health Administration

I wanted to follow up on the electronic prescribing issue, and Patrick isn't here, but CMS puts opt out related to that in their rule about electronic prescribing and it may be helpful for the certification criteria to be consistent with what CMS did for the incentives for electronic prescribing, specifically for rural areas. So if you could survey and you could say in my area there's one pharmacy, it's 100 miles away, they don't ..., then my goal was zero percent and I could still qualify for, there were some other caveats, but CMS has worked this a lot and it would make sense, I think, to ensure that what this rule is, is consistent with whatever the CMS final language was.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Good point. If we're ready, we can move on to category two, which is engage patients and families.

Farzad Mostashari – National Coordinator for Health Information Technology

Before we move on, Paul, you had mentioned in the problem list, the maintaining problem list, that there might be times when it would be important to actually test the completeness of that diagnosis, which was brought to mind actually because around hypertension there's some work that Nirav Shah, actually before

he was State Health Commissioner for New York had done some work with Geisinger and others looking at the completeness of, and Northwestern I think has done some interesting work around this, that a lot of people who aren't getting treated for high blood pressure, they have repeated high blood pressure measurements but no diagnosis of hypertension, and that is actually a significant portion of folks. Are you suggesting here that actually such a test be actually proposed or, I don't know if it's a quality measure or if it's on the road map for Stage 3, I understood the point about it's important to have completeness, but I wasn't quite clear on what the policy implication of that is.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

I think we were looking at Stage 3 to start introducing the capability of doing exactly what you said, so diabetes, hypertension, a lot of these things, the data's already there and it's not necessarily even that the users want to ignore it, they just need some prompting, just like any other reminder. And because there's such high leverage and the more we teach them and the more accurate it is, the more benefit downstream, it starts a positive feedback loop. So, yes, we were hoping in Stage 3 even to start to address ways the EHR can facilitate maintaining complete and accurate lists. So category two, and Christine?

Christine Bechtel - National Partnership for Women & Families - VP

Thank you. I just wanted to raise one thing around secure messaging. I'm okay with following the threshold, as we've talked about, but I also had another idea occur to me that I want to put forward for folks to react to, and that is whether or not we could consider a two part secure messaging requirement. One would be that it's actually the provider doing the sending of the messages that are patient specific, but that there is then a timeliness requirement for responses to any messages that the provider receives back from patients, or just receives from patients. So that might begin to address, I think, what some people are worried about, and we'd have to say definitely patient specific, but the idea that the systems can easily measure response timeliness, and so if we said you need to respond to messages that you receive within two business days, then the impetus is definitely on the provider, they can be tailored to individual circumstances, the threshold would be higher than 5% because I think there are more reasons to communicate from provider to patient in that respect, but then having the timeliness of response rates I think is something that would make this actually very useful for patients.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

We'd also invite comments on the 10% of patients seen have viewed their record. That was one of the measures that was proposed. Larry?

Larry Wolf - Kindred Healthcare - Senior Consulting Architect

I guess this comment is more speaking as a patient than any other role. I agree with you that the goal is really to engage patients, and that happens best when it happens live in the office when someone hands me, here's a summary of what just happened and we can quickly go through it and I can go, yes, yes, yes, oh, I have a question about this one. To get it two days later, now I'm playing phone tag or e-mail tag or something tag with the provider saying I don't understand what I'm supposed to do about this thing. I thought I knew, but now I don't know. I know it's very hard to get that into regulations because there are always exceptions, but I think it's really important to maintain that the spirit really is about engagement. And I'm concerned, I hear discussions, even if they're meant jokingly, of developers being handed regs and saying here's the spec, go build to this, or providers doing the same thing. Oh, I only need one problem on the problem list, and that's clearly not the message we're trying to communicate. So I think the discussion has had that richness to it. I hope it winds up in the comments to make the distinction what's sort of regulatory because there are reasons for exceptions, but what might in fact be best practice.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

It's probably worth sharing the discussion of the workgroup around this. The NPRM suggested that instead of having, in fact, our goal was to really have this stuff available immediately, but then we also recognized that some lab test results don't come back right away, so we had this two timeline approach and the NPRM was saying there's a lot of confusion that's caused by that, and so going to a single timeline is better. And so that's why we compressed it, as George said, as the outer limit of time and

made it two business days, expecting that essentially it's in everybody's best interest to have the patient have their ... summary or clinical summary right on the spot. And then providers will recognize that hopefully.

<u>Larry Wolf – Kindred Healthcare – Senior Consulting Architect</u>

Maybe this is a good place to jump in with a related comment about the materials we supplied to the patient versus the materials we supplied to other providers. Since the patient is often the bridge to the other providers, I think it's really important that whatever we give the patient speaks both languages, that it says you have this heart condition and puts it into people speak and also names the heart condition so that if they take that paper with them, that the other clinician actually has the relevant details and isn't going, this isn't really helpful, I know you have a heart condition. I'm a cardiologist, and that's why you're here. What does the primary care doc think was really going on?

<u>Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO</u> Gayle?

Gayle Harrell – Florida – House of Representatives

Thank you. I just want to express a little concern about the threshold of 10% on secure messaging. Given the digital divide that still exists in this country I have a real problem on specifying percentages. Certainly we originally made a recommendation of a specific number of patients which you could most likely attain, but when you get into percentages and you get into different populations, this may become very problematic, and again, I don't want somebody not to qualify because of things of that sort that are truly beyond their control.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO David?

<u>David Lansky – Pacific Business Group on Health – President & CEO</u>

I just want to go back to Christine's suggestion, and I just want to endorse it. I think re-thinking this, partly in light of Gayle's comments, to talk about whether the providers are pushing messages out to their patients and then responding in a timely way when patients choose to respond in an electronic format is valuable. I also think the 20% threshold that is proposed for the recording patient preferences might give us some visibility into how many patients are choosing to exchange messages electronically that could be used as a denominator of a revised measure.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Any other comments on this section? I'll just open it up one more time, because we did have a lack of consensus in our group about the 10% view information in the record after a visit. What ... do we have from this group? Gayle?

Gayle Harrell – Florida – House of Representatives

Again, I want to say we have a digital divide in this country that is extremely difficult and here, again, you're holding the physician responsible for things that are totally beyond their control, totally. I have a real issue with that.

W

We did do some work to think about the exclusions in cases where there was really low penetration, and I think we need to revisit that. I think there are federally designated areas that are known to be very low broadband access, and I think we absolutely could revisit that.

<u>Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO</u> Terry?

Terry Cullen - Director, Health Informatics, Veterans Health Administration

This is Terry. From my old hat of caring for American Indians, Alaska natives, I have to echo this, what we know is less than, depending upon where you are, less than 20% of people have broadband access,

with some 1% have access at their homes, so if you give a 5% number, though, I really am intrigued by doing this measure different and changing the denominator to what you said. It may be difficult to do, but if the patient indicates that their preference is electronic communication then we somehow figure that into when the physician has sent messages to that patient with the expectation that you are communicating with your patient and then how timely the response is. So there may be a way to get at it without penalizing, and actually I think it's more than not penalizing, it's having the broader community recognize that there really is still a digital divide. There's probably a two-pronged benefit from that.

<u>Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO</u> Christine?

Christine Bechtel - National Partnership for Women & Families - VP

My guess is that for David's idea around the denominator changing, that's probably maybe something that's more for Stage 3, where once we have that information collected you can have a much higher threshold for patients who indicate that. My suggestion around secure messaging is really meant to make it useful to patients. I think the online access, though, is very, very different. That is something that we know from survey research that two-thirds of Americans really want, and actually higher rates of some sub-populations, like Hispanics, and I think in my view it is, in the interviews that we've done with providers who have offered the online access they say it really makes their jobs a lot easier and it really puts the patient's workflow at top of mind and it begins to, like we have in the quality measures rule where we have these debates around provider accountability for things like blood pressure control, we have gotten past those and we have had the right exclusions in place. So I think this is a case where we do need to address consumers' fairly low expectations of the healthcare system and the ways that they communicate, but I do think exclusions around broadband access are appropriate.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Okay, are we ready to move on to the next category which is care coordination? Christine?

Christine Bechtel - National Partnership for Women & Families - VP

Back again. I have a couple of comments here, and some of the discussion I want to hold for when we hear from Micky about more of the workgroup's discussion there. I don't have a recollection of agreeing to defer to the IE Workgroup on the case of the Stage 1 options and what we do in Stage 1, and my concern there is that if I read the chart right in the NPRM, and that's a big "if," I think you actually have until 2017 or 2018 to start Stage 1 if you want. So we need to think about the providers who, well, I'll give you the chart, it's right here, but nonetheless it's more than just one year of providers who will be affected by the Stage 1 criteria, so I do want to make sure that we're providing the right kind of on ramp and escalator to set the stage for Stage 2. So we can talk about that more, but I do have one thought around care summary transmission, which is I'm not sure that the certification criteria and the meaningful use policy rule will foster the ability to not just transmit and receive a care summary, but to be able to actually incorporate that data automatically, whatever fields the receiving provider would like, into their EHR. And it seems to me that that is a critical capability that needs to occur, so that's another dimension that I want to raise and think about how we foster at least the technical capability for the EHRs to be able to do that.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Do you know who went first? Larry?

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

Thank you. I actually want to pick up on Christine's notion about how to do messaging, and maybe that's a way to think about some of this piece on care coordination. I think that the notion of having no walled gardens where people get to say this is my world and I'm only playing with the folks I'm playing with, I think we want to dispel that. We really need to facilitate communication among all the relevant providers, and we can't, from an IT side, dictate organizational structure or technology adoption. So to me that gets at questions of if someone asks for something can you supply it, and are we imposing artificial constraints on what it means to supply it? So I'll speak from the folks who may not have, for various reasons, certified EHR technology, but are very interested in receiving the information. And so I would very much like a provider who has a certified EHR who's getting incentives to send me, here's a summary of what

happened when the patient was in my care, and send it to me in whatever way I can get it. So if I get that through direct, for example, send it me to my direct address, and that should count for the sender. They used an approved method to send it. If it means that my local community has a health information exchange that provides for hosting things on my behalf and they send it there and I view it through a portal, that that should count.

And so the rule talks about the receiver has to have certified EHR technology and I think we should consider broadening that to some of the other things that we're looking to encourage and allow that as an acceptable means to get it. Okay, so let's broaden the context a little bit. I don't know what to do about where the threshold ought to be on this and how to configure that. I'd like it to be if someone asked you have to send, so that we're not allowing people to say, well, I don't want to deal with you. Sorry, I'm sending it to you slow boat, bulk rate mail, you'll get it in three weeks. It's not my problem because I don't want to encourage patients to go to see you. We don't want to use the technology to make that worse. But I also don't know how to measure the request, so I don't know how to say let's put this in a numerator or a denominator. You have to respond electronically to all the requests you get electronically. I don't know how to measure that, so I don't know how to propose it, but I think that's the spirit of response when people ask, and don't artificially discriminate when you're sending summaries out, you have multiple ways to send them and you should use them.

I think actually what's happening with the prescribing might be something worth looking at, where many of the pharmacies that are not really eEnabled get a fax that the agency that's sending the message goes, oh, this pharmacy doesn't have electronic, I can still take it electronic from the prescriber and turn it into something that that pharmacy can accept. So I think we should be looking at something similar here to take the burden off measuring what the receiver has and put the burden on the sender to say, send them, and we'll allow ways for the receiver to get it.

I also want to pick up on the comments about needing to do more than just receive a document. That really, I think is directionally where we need to go. I've been very unhappy with the slow adoption of smart receipt, if you will, that this document comes in and it's structured and even if there are coding issues there are still ways to work with the structure of the document to go, oh, here's a list of the meds. It doesn't have to be a ... I don't have ... document. Here's a list of the meds. I can deal with them one by one. Here's a list of the problems. I can deal with them one by one. So I think we need to be encouraging the ability to bring in that structured information, but recognize it may not be fully coded or it may not be coded in compatible codes and embedded in the reconciliation process that we're talking about, that those are very important things to set as guidelines and to be looking to the vendors to provide. I don't know if that can be done in a Stage 2 timeline, but I think with our notion of trying to send directional signals, that we ought to be saying this is where we ought to go, you ought to be able to bring the document in, not just as a document but a structure with perhaps shades of gray in the structure and look to create that as a very clear part of our road map.

<u>Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO</u> Gayle?

Gayle Harrell – Florida – House of Representatives

Thank you. I think care coordination's probably the most important aspect of what we do here, that is where we're going to get the bang for our buck out of everything that we are doing with incentivizing EHR adoption. It's critical to make this happen. And this is probably our weakest link, when we think about how you're going to incorporate the disparate records together from the various vendors, and this is where those certification standards are going to be the most important thing, because what I hear again and again and again from all the providers out there is I have a wonderful EHR, somebody else does and we want to exchange, but we can't. And you've got to have that ability to exchange. The HIEs are trying to stand up, are trying to do interfaces and it is a nightmare and it is expensive to do this. So we're at the cusp of right now getting down to the core issue of exchanging data, exchanging discrete data that can be incorporated into various electronic records and vendors. And if we back off and don't continue to move to require that we set up those standards and we make it happen, we're wasting time and a huge amount

of money. This is the key element. We're not going to be able to have HIE, we're not going to be able to have exchange of data unless those certification standards are there, and we've got to do it now.

<u>Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO</u> Judy?

Judy Faulkner – Epic Systems – Founder

I agree with Larry that if a patient goes to another health organization and wants his or her data moved over it shouldn't be a decision between the healthcare organizations, it should be the right of the patient to move the data over. I did want to mention one thing that we've run into, it doesn't seem to me that the concern I have heard is as much, well, sometimes it's stealing patients, so that is one concern, but the other concern that I've heard that was particularly fascinating is that if I'm a healthcare organization and a patient goes to my ED, it's just a normal ED visit. If the patient goes to another ED I have heard charges ranging from \$4,000 to over \$20,000 for the patient to show up in the other ED, and so that's been some of the concerns of why people don't want to share. I don't know how we would handle that here, but I can see that that is a concern. And some of the ideas that have come up are things such as if the patient has a life threatening illness certainly take care of that patient. Send the data over, but have an agreement that says if the patient has a life threatening illness, take care of it, since the patient is using this as a primary care, use it, and then the organization who's sending that data over gets the opportunity to pick up that patient and take that patient elsewhere. So it's an interesting quirk that we're seeing.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Any other comments? We'll move to the last category, which is population and public health. Marc?

Marc Probst – Intermountain Healthcare – CIO

Thanks. I had a couple of questions. I think the value of EHRs is you're improving the care of the patient in front of you through care coordination, like Gayle had mentioned, you can coordinate better, and then there's a population health component, and registries are obviously one potential mechanism to accomplish that. I wasn't quite clear in the discussion here about how people view, is the concept of registries only to proprietary registries, it seems the focus. There's an enormous amount of potential for public health registries. The immunization registry may be the one, and I wouldn't argue that that is a pretty important core one to have ... for surveillance, but there are a whole bunch of other potential registries that could be set up that could give you tremendous value.

As you may know, we're looking for innovative ideas in Maryland about how to use health data, and we're running a contest, and the number one idea in the contest is create a registry for sickle cell patients around their reactions to transfusions, because you don't know when the patient shows up whether they've had a reaction at some other hospital. And there could be a whole bunch of different things that could have a lot of value to clinicians and patients, and I wonder two things. I wonder whether the concept of different kinds of public health registries is part of this, whether the committee could support that, and also if you're looking for clarification about what's an acceptable registry I think that the support of the public health department or a federal public health agency like the FDA that this is a registry that has value for public health to really understand whether something is working or not would be a pretty good standard for what would be an important registry.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

I think, to answer your question, you're right that this is addressing specific comments we heard at our hearing and they were proprietary databases. And I think you're right to point out that we're not paying enough attention to the other registries. One issue was registries tend to have a lot of data elements and one of the problems is there's not a standard to describe all the data elements, and the second was, if you turn this into certification requirements then you'd almost think that every EHR vendor would have to interface with every registry, and that's something we were trying to figure out how to deal with. So we weren't at all trying to exclude the kind of public health registries you're describing and we need to probably pay more attention to the wording there.

M

Certainly if there's a kind of data standard that would allow submission of data to multiple registries, that it could do that and then it would be up to the state or public health entity to try to either require or do it whatever about submission. But there's an enormous amount of, I think, potential through this, because even in states like Maryland where we have the Health Information Exchange a lot of the EHRs may not be connected. So we can get a lot of information from private doctors that could be directly relevant and get people information at the point of care on a particular issue.

Another one that comes up that we're doing, which is advanced directive registry, and it's great if you have an EHR that says whether you have an advanced directive, but if you show up at an ER and you don't know and there's no communication about it, that you could set up a standards or an advanced directive registry that would then make sure it had the most up to date information for people, that's something we're looking at too.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Great. I think I saw Terry and Marc.

<u>Terry Cullen - Director, Health Informatics, Veterans Health Administration</u>

I had a couple of comments. I think, as people know, at Indian Health Service we had to write about, I think they're up to 22 different interfaces to submit to state immunization registries, and I agree that that is a pivotal one and if you get that one maybe we have a chance here. But my concern is that by saying you now need to submit syndromic surveillance data, which obviously IHS was able to do all this, but it meant we had no architecture that made sense. We, in fact, developed different ways of submitting to the different registries not over the same line and I'm wondering if the comments about information exchange, and I think information exchange in many ways is in its infancy when you look at the number of actual exchanges that have occurred as opposed to the framework being established, but I'm wondering if we're doing a disservice by saying, okay, now we want you to submit to a cancer registry and now we want you to submit to the newborn screening registry, which I actually thought was going to be the next one we did, and whether there needs to just be a step back and try to figure out longer term with an interim step what makes sense, because asking people to submit to five different proprietary registries in the next three years, because we're going to have Stage 3, is going to be difficult. I don't know the answer to this, but I just have some concern about doing these significant, in a sense, one-offs that are disease specific.

<u>Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO Marc?</u>

Marc Probst - Intermountain Healthcare - CIO

You may have answered this question, but if a state has a Web-based immunization registry that's currently in use does it require that the EMR automatically link to that, or can still the state provided Web-based immunization registry fulfill this requirement?

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

There may be other people that can answer better, but I don't think entering into a Web-based registry for your state would qualify for the EHR Meaningful Use objective. Can anybody else –

W

... certified. You have to show that you are transmitting electronically into an immunization registry at the time of certification.

Marc Probst - Intermountain Healthcare - CIO

Okay, there's a lot of workflow based around that decision as that stands, the way we're seeing it.

<u>Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO</u> Josh?

Josh Sharfstein - Maryland Department of Health and Mental Hygiene - Secretary

There's a lot of workflow around entering in all your immunizations for your patients, whether it's hard copy or by hand or online, so the idea is that it can be simpler. And I realize that this is a challenge, but there's such potential for medical information when you get up to a level where people can access it and there's just so many different ways that it can be used that I would hate to think that the fear of having to figure out the standard or the fear of a few different things, the key is that they're really important, immunization is extremely important. A state that went ahead and collected 20 registries on things they weren't going to use, it wouldn't be valuable. But there's just such tremendous public health value if you can bring together information a certain way, and where the exchange can do it, the exchange can do it so it doesn't make any extra work for anybody, but there may be particular areas where you could save a lot of lives by having data available, and that's the kind of feedback we're getting now. And I just hope that as we think there's so much focus on the clinical encounter that we realize that kids die from transfusion reactions and if you can prevent them by having the data at the point of contact, that's a huge potential value.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

I think there's a tremendous amount of value in that. There's so much value I think we ought to come up with a standard and figure out how to get this done so that we're not building 10,000 different interfaces. And this requirement is going to do the latter. It's going to mean a lot of interfaces that aren't based on standards and I think we ought to focus on that versus this interim step.

<u>Art Davidson – Public Health Informatics at Denver Public Health – Director</u> Paul, this is Art.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO Go ahead. Art.

<u>Art Davidson - Public Health Informatics at Denver Public Health - Director</u>

Yes, I agree with Terry's comments and Marc's comments most recently. I think that we are working toward that standard and unfortunately this NPRM will not get us there, and in Stage 3 the S&I framework work that is being led by ONC and CDC will hopefully get us to a place where we won't have proprietary standards, there will be essentially one standard to communicate with many different registries through Exchange or through Direct, whichever. And back to the point that Farzad was making earlier, these chronic disease registries that have been used around the country also could benefit from that standard and address some of the things that Josh said about saving lives and improving the quality of care, so we're short on this with Stage 2 and this was a stretch to have some of these things in here. We are definitely working toward achieving this standardization that we all would like.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Thank you. This has been very helpful. Judy?

Judy Faulkner – Epic Systems – Founder

I absolutely agree with needing standards for this, because it's going to drive everybody nuts otherwise. One other thing I wanted to throw into this which I think is interesting is for those vendors, and a number of them do, who work overseas as well as in the U.S., a lot of the overseas countries are looking at the U.S. for the standards so that we can all be a world not just a country. And if we have no standard, we just have multiples, then guess what happens overseas? There are more multiples. But if we can come up with standards then it sets an example for other countries to follow so that they can all have the same thing.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

That's been good input. We're going to have to get some more feedback on the standards on these registries. Any other last minute comments, because I think we're over our time. But it's been a very, very helpful discussion.

W

Are we going to talk about team-based care? Sorry.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Why don't – okay, I'm getting two signals; one is one minute and 60 seconds, not because it's not an important topic, but just that we had –

W

I want to focus on, Larry brought this up earlier and I think that this is really critical, I think we need to figure out how to support it. And I recognize the difficulty in the measurement part of it, so what I'm wondering is if you attest under team-based care, and I don't think it's 25 providers, I think it can be a team of 2 providers, a physician and a PA, is there, first, something you answer about how you share patients or something, and then you can give aggregate results for your team in terms of quality measures. I haven't really thought this through, but I think that we will mis-message this if we don't take this on, and CMS, and I regret Patrick isn't here, I know is really struggling with how to support team-based care because it's obviously where there's a lot of emphasis.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

So as not to cut off this concept I think David is going to cover this, because it gets re-addressed really in the Quality Workgroup, not that we have the answer, but we really could benefit from more discussion about this. I don't think any of us have the answer, but if we can get some more ideas that may be novel but simple, then that would be greatly appreciated. Thank you so much for the input. We will take the input from this group and work on it as a workgroup and then bring you back our revised results next month. Thanks a lot and we're next going to turn to the Information Exchange Workgroup that Micky Tripathi's going to lead.

Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO

Good morning. Thanks. I have the great privilege and I'm happy to have the privilege of representing the discussions of the Information Exchange Workgroup. I would propose, given that we have half an hour and I know there's going to be a lot of discussion, that instead of going through IE Workgroup charge and our overall agenda, that we just jump right to the summary of status or discussions. So I guess I'm the one who controls that. What we've done is we've taken a number of the objectives that we thought in working in conjunction with the Meaningful Use Workgroup that we categorized as being explicitly related to information exchange and then taken those as the focus areas for the working group. We've at least had first level discussions on almost all of the ones that you see there on the dashboard, except for the last two, View and Download, and Secure Messaging. Those will be discussed in a meeting that follows, so we don't really have anything to say about that.

As you can see, in a number of them I categorize the status of our conversations in one of two buckets. One is either that we've come to a decision and we're ready to really document that, so we're feeling pretty comfortable with that as a preliminary recommendation, obviously subject to comments from this body and from others, and then the second category are things that require some further discussion. We had a first pass conversation, in some cases we've identified areas where we want to do a little bit more fact-gathering, so we're headed toward a consensus but wanted to get some more information and we're in the middle of gathering those. Or in others it was just a complex issue and we couldn't handle it in the 90 minutes or whatever we had, so we just need more conversation about it.

As you can see here, we've come to some decisions and consensus views, I know some of them it may be misleading because some of them say unanimous and some of the other decisions don't say unanimous, but all of them have been unanimous. For the ones that I've marked as decisions there hasn't been any dissenting views for those. What I'd like to do is just break it out into two. On the next slide I go into a little bit of detail on the areas that we have come to a decision on, a little bit of the rationale for that, and then on the subsequent slides cover the ones where we are still investigating certain areas or we're still having conversations. So please feel free to interject at any time.

On the first one that we've already come to a decision on is one that actually was not a part of the NPRM, it was a recommendation that came from the Policy Committee, was then not taken up by the NPRM, but the workgroup would actually recommend that it actually be restored, and that would be the requirement

on hospitals to send structured lab results. It was, as I said, a unanimous decision in the working group to restore this, and basically there were three main points of conversation about why we felt pretty strongly about this one. One, the NPRM notes the concern that this would be a burden on hospitals. In our conversations there was a lot of conversation about the reverse, but actually in many ways many hospitals may not see it as a burden and in fact some hospitals might find it beneficial to have a standard rather than having to have a lot of the optionality that exists today, both within the organization and in dealing with different EHR vendors who asked them to come and meet them where they are, rather than there being able to say this is the national standard. We don't deliver according to a national standard. And you can see that in one of two ways, but there were certainly some of those views expressed by hospitals who are represented on the workgroup, and the experience of a lot of us who work with community hospitals have gotten the same view.

Second, we're just very concerned that by not having this requirement on hospitals it's the last piece of the puzzle, we're requiring that EHR technology be certified to receive according to a set of standards. We're also requiring that clinicians have a certain amount of their labs be structured labs but we're not requiring that the last piece of puzzle that's responsible for a large fraction of those results deliveries, we're now requiring that they be required to meet that standard. So that's the concern that we have about that, that it directly affects the eligible professional's ability to meet their requirement related to structured labs integration, and that it also will directly affect clinical quality measure capabilities with a wide variety of the measures really slow us down there.

The next one, perform a test of HIE, I think Paul and George mentioned this one, we did agree to support the NPRM recommendation to remove that as a test for Stage 1 and we also agreed with the option that they had recommended, which was option one, which was to not replace it with anything else. Our thinking was as follows. One, that there did seem to be a lot of market confusion about the measure and by CMS' reporting a lot of people ran away from the measure, a lot of people were so confused about it that they didn't even do it.

Second, we wanted to minimize the addition of new requirements in Stage 1, so that was why we really didn't want to go for option two, three, and four, recognizing that there are going to be a lot of other things that are going to be probably added to Stage 1 for those who haven't yet attested yet. But I think the view of the workgroup is we don't want to add to that problem, so let's not do it if we don't have to.

The third, and we may have gotten this wrong because it only affects those attesting to Stage 1 in 2013, there's probably a longer tail, but it probably only goes until mid-2014, so there's really a relatively small group, a small cohort that it affects, and assuming that they're going to be anticipating the requirements for Stage 2 and that there's a full year requirement to attest for Stage 2 from the beginning there was a sense that there's enough pull from the Stage 2 requirements that it didn't require this one.

On the next one on public health, we are still in discussions around a bunch of the issues related to public health generally as well as the immunizations and the electronic lab reporting. However, we did reach a consensus on one particular aspect related to syndromic surveillance, which was to keep the requirement on eligible professionals as a menu set item and not move it to core. I think originally the IE Workgroup had recommended about a year ago that it be a menu set item, I think the Policy Committee recommended that it be core and presented that to CMS, and now the NPRM is recommending that it be menu set. For all the reasons that we articulated before, we feel pretty strongly as a workgroup that it's appropriate to keep it as a menu set item for eligible professionals.

Then finally on transition of care summaries there's a lot more conversation to have, so I don't want to suggest that this is the only thing that we'll be addressing in the transition of care summaries, because there are many dimensions to it. But the one area that there was workgroup consensus on in the conversations was to remove the cross-vendor requirement to meet the 10% electronic exchange threshold, so you may recall that for that 10% threshold it says that you need to be able to have 10% of those transmitted electronically to organizations that you're not affiliated with and who are not on the same vendor platform. We agreed with the first one, but not with the second. In many markets, both rural and urban, there is a single vendor that has high penetration

We also felt that what we want to be able to do is create an incentive for vendors to incorporate the national standards deeply into their products, and at least the one EHR vendor that's represented on the workgroup had represented that they actually had done that. And what we want to be able to do is encourage that and encourage others to do that, and by saying that they have to do a cross-vendor thing it almost created two tiers, they might be doing something proprietary that was deeply integrated with their product, but then have this other second tier and perhaps lower level of integration for the national standard.

And then finally, we don't want to force "artificial transitions" in order to meet the requirement to the extent that you genuinely don't have any transitions outside of those two categories, if people are artificially doing things just to meet this. So those were the areas that we reached consensus. There are a lot more areas that we still have to discuss. I'll just walk through these very quickly in terms of some of the high level issue areas so that we can reserve time for your questions.

On the electronic prescribing, we had a concern, similar with the conversation with the Meaningful Use Workgroup, that the threshold may be a little bit high given the state of the market. The areas that we were pointing to were, as Paul had noted, patient preferences being a significant driver, but the two areas that came up in the conversation were related to wide geographic variation in ePrescribing penetration. and in particular relatively low penetration among mail order pharmacies. And so we had one clinician who's a very sophisticated clinical user and EHR user on the workgroup, who practices in Massachusetts, which as you know is the number one ePrescribing state, reporting that because of low penetration in mail order pharmacies he himself might have trouble getting to 65%, which for a practice of that ... I think would be an indication that this could be troubling in a lot of environments. So we're actually waiting on more information from Surescripts, who are going to give us more information on penetration of mail order and geographic variation. We also did take into account that we're not talking about now, so one thing to consider certainly is that if we set it at 65 that makes that a goal and creates pressure on the mail order pharmacies to increase their penetration between now and when Stage 2 begins. So we certainly recognize that and want to be able to be looking toward where this is headed and try to create those inducements, but we want to make sure that it's something that is genuinely achievable for clinicians and the things that are in their control.

I'll just skip over some of these and just hit the highlights on various categories. In public health there was a general concern, as again, the Meaningful Use Workgroup had noted that we had about too much discretion left to state and local public health agencies. We didn't talk in particular about the "except prohibited by law" part of that, so we can take that up in the Meaningful Use Workgroup. So we weren't really addressing that when we were talking about too much discretion, but it was more about the lack of definition of ongoing successful submission, for example, that there was a lot of optionality allowed in the standards that we thought didn't quite make sense given some of the requirements that were being put in the transitions of care kinds of electronic transmissions.

We also thought that there should be greater alignment with the transport standards in the EHR certification standards that were being articulated for the transition of care summaries. On immunizations there was a concern about wanting to better define which immunizations would be covered by that, so is that just the immunizations that have happened in my practice, is it every immunization I have a record of, again, just a detail but something that we thought needed a little bit more specificity. The general concern about the registries in general, let alone the cancer registries or the specialized registries, was mostly about the definitions. We thought that we needed a lot more specificity on the definition of what would be qualifying registries, both with respect to what is a state registry, which is a term that's used there, but more importantly with the specialized registries, for all the reasons that I think were discussed in the Meaningful Use Workgroup. There are proprietary registries, there are all sorts of things, and it seems like a lot more specificity is needed there.

Then finally on the transition of care summary, the 65% requirement, there was some concern about the excluding cases where access was already provided through the electronic health record, so what that would do to a number of organizations, it would leave them with a subset where perhaps they hadn't built

anything electronic. I know that's the goal here is to try to push that, but there were organizations, some of which might be even fairly sophisticated, who were pointing out that that might be a difficult thing to achieve. However, I think when you look at it a little bit more, and this could be a conversation for more discussion in the workgroup, given that the requirement for the 65% is only that you generate something and you can even hand the patient this paper and that would count, that might ameliorate some of those concerns. We just didn't get that far in the conversation.

There were concerns about the exclusion criteria related to small numbers of qualifying transitions, so the concern there, and I know it's a little bit of an obtuse phrasing, the concern there was that what it says is that exclusion criteria that if you don't have any transitions then you're excluded. But the concern was, well, what if I'm an orthopedist and I only have four of those qualifying transitions, how do I get 65%? And so the thought was we should probably have, we need exclusion criteria but maybe it should be a way to come up with a number, but that zero was probably too much because you get into these weird small number sorts of issues with respect to the measures.

Then finally, on the med reconciliation there was a general concern that 65% might be too high for some specialties, where the concern was more just about wanting to check what those exclusion criteria are because this is being proposed to be moved from menu to core. In Stage 1 it might have been okay because people could run away from it if they wanted to, but now that it's being proposed as core, I think, as we discussed in many other settings that for certain specialties med reconciliation could be a hard one depending on the specialty. That's where we are in general. I'm happy to answer any questions or take your comments.

W

Thanks, Micky. This is really helpful. You guys looked at a lot of the issues that we struggled with too in the Meaningful Use Workgroup, so I really appreciate it. I really appreciate your recommendation on structured labs for hospitals. I think that's really Terryfic. On the care summary ... performing a test of HIE, I did get some clarification, and Farzad will correct me again if I'm wrong, but everybody starts in Stage 1, like forever, so what I'm worried about is there's no building block in Stage 1 to get to Stage 2, which is really supposed to be about Information Exchange, so it would make more sense to me to require one transmission, I think that's the fourth option, one successful transmission. And I think particularly as the market is evolving you've got more meaningful users out there capable of receiving, you've got Direct becoming more and more prevalent, so I think there are a lot of ways that the market confusion will decrease, and in no small part because in Stage 1 we never defined, or CMS never defined, what the care summary was in terms of content, so that's been remedied in Stage 2. It would make sense to pull some of the dimensions from Stage 2, as proposed, back into Stage 1 to clear up the market confusion, but then still really give people a building block, since this stage is going to apply over time, and also because of the proliferation of new models of care like ACOs and PCMH, where we really do want to get that functionality in place. So that would be my first comment. I don't know if you want to react to that. I do want to talk about the care summary in Stage 2 as well.

Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO

Yes, we didn't talk specifically about option four, I think, in the workgroup, so I can't really represent what the views would be there. I think in general there was certainly a sense that if the other parts of the NPRM related to transitions of care were adopted for Stage 2, and given that it was a full year and given that it was affecting a relatively small cohort, wanting to move away from test the technology kinds of things and get us more toward just do the thing, that there was enough pressure there to at least have the workgroup feel confident that it would happen without having what might be sort of a check the box kind of thing more than anything else.

W

I understand the test idea was definitely problematic, but it might be something for the workgroup to reconsider since I think it's actually not a small cohort, right, Farzad, that this would impact? It's not a small cohort because it would affect all Stage 1 entrants, period, coming in the future years. I think that's a big deal.

The other thing actually might be to take a look at the standards and certification rule for Stage 1 because I think that it's my understanding that transport standards were not included in Stage 1 and that would really facilitate if you had that combination of transport standards and then the requirement for one single transmission, I think that would facilitate, clear up the market confusion, get people capable of it, and get them doing that in that stage for years coming.

The other thing I wanted to know if you thought about in terms of the transmission of care summaries for Stage 2, one thing we've really struggled with is having a fairly low threshold for electronic transmission, which is 10%, and yet we should see over time, particularly as Stage 2 spans more and more years, more and more meaningful users, more and more people with systems that are, maybe we call them meaningful use compliant, more and more people who are using Direct, not just eligible providers but long term care settings and others that have the capability to send and receive information. So we in the Meaningful Use Workgroup struggled with how do you really begin to foster meaningful exchange outside of your organizational boundaries but at a higher threshold than 10% and is it worth looking at the denominator of, well, if you're sending to a meaningful user and we know who they are, then the threshold is higher, or some other kind of alternative that would really foster more electronic exchange.

Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO

I don't know how to react precisely to it. I think that we did have a little bit of a conversation about the complexity of the 10% and specifying a transport standard related to that and where the market is, and there was just a little bit of conversation, and I don't know if this addresses your question directly, about with all of that confusion out there and trying to parse out what's a qualifying transition for this, because the numerator and denominator changes a little bit ... 65% and 10%, that it seemed appropriate I think in the context of that conversation to keep it relatively low for now just to get people started, have it high enough that it's meaningful so you can't ignore it, but have it low enough to at least provide the flexibility for people to make the adjustment over time. But we can certainly take it up again and bring it back for —

W

... my concern is just that it's supposed to be the information exchange stage and I don't think we're there.

Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO

Right. Well, another dimension ... hit on but did come up in the workgroup that I think we'll take up again before the May final recommendations are how do we count polls to the extent that you have certain settings, perhaps NwHIN exchange settings, where the example that came up in the workgroup was an emergency department, so what if they are in a setting where they can actually query an ambulatory practice for an ED patient who came in and they're able to do that and they're able to get the information back. There's nothing right now that would allow them to count that, and I think there was a sense in the workgroup that it would be great to be able to do that because they're starting to move to where we would like them to be able to get. It's not obvious where you would count that, because as you think through whether you could count that as a part of this you start to get into these weird counting issues of, well, who would get the credit for that information flow. But I think that there is a precedent when we think about, I think in the 65% measure which does allow at least you to take off the table cases where you've provided access that basically says you don't have to provide a formalized summary if you've given access to the electronic health record. So there may be some precedent there that we can work on to try to see how we build pull in and create some incentives for that without getting beyond the germaneness and logical outgrowth restrictions that we have on NPRM comments.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Gayle and Judy?

ΝЛ

Thanks, Micky. Looking at the fact gathering slides, the last one, and looking especially at the public health registry reporting and maybe the transition of care sections, and I'm thinking back to Terry's comments about the pluralism of registries and the difficulty of figuring out standards by which to populate those registries without trying to do them one by one, and it seems like we need to work toward a model where the aggregate publishing of data from the EHR to these various reporting functions gets easy and

flexible and adaptive, and not case by case by case. And I'm wondering, so splitting out in a sense the transactional information exchange stuff, getting the lab results and pushing individual packets around to populate the record between providers from this aggregate reporting functionality and drawing a line on this slide and thinking of ... as two separate classes of transactions to think about. And the second one, the one that is the aggregate reporting to registries of various kinds, public health, specialty registries, whatever, immunizations, we need some kind of intermediate architecture and platform to handle that stuff that takes data like CCRs out of the record and then manipulates them and translates them to other uses. The pop health platform that's been developed does a version of that for clinical quality measurement, and I'm wondering if the committee has or could, ... the rest of your work plan this year you're going to be thinking about these several types of reporting, and start to think of them as a class not as individual cases, and think about is there a pop health-like platform, maybe it's an extension of pop health which actually has built into it a population health reporting database that's supposed to feed immunization registries that would be a version of IE that is meant to support these aggregate reporting capabilities so that we can get away from having to specify each one separately.

Now the problem with that I think with the opportunity is to rethink are we defining the summary documents, whether it's CCD or the care summary documents or others, adequately to support the functions that are going to be needed by these registries, and is the clinical data for sickle cell reporting, whatever it's going to be, is it in there now in a way that could be then extracted from an aggregate reporting layer. I do think for Stage 2 there's a long way to get to a point, we have to have at Stage 2 the invitation to capture the data we will be needing later to populate these other functions and I'm worried that if we don't think this through pretty quickly the record won't have the data needed to, even if we do create this intermediate layer, to populate these functions that are all needed for various purposes.

Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO

... and see if I can address that and consider that. I think that we did talk a little bit about, and this is related to a part of your question, of there just being the challenge of what are the content requirements for the different registries and how do you sort that out in a basic EHR certification versus an oncology specific one, and there are just going to be varying degrees of granularity depending on the specialty and it just wasn't clear at all how that all would be worked out.

<u>Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO</u> Gayle?

<u>Gayle Harrell – Florida – House of Representatives</u>

Thank you. I want to go back, again, to the elimination of the 10% of exchanging records with another vendor. I think you've made the statement that you want to incentivize the incorporation of national standards deeply within products so that there is that ability to exchange if you eliminate the requirement that you do exchange with other vendors. Are you going to make specific statements that make it very clear that we've got to move to national standards and that part of the certification process is that the standards are in place and that the product must have those embedded in them to allow the exchange, because I can tell you as these HIEs are standing up, they are having a very difficult time in the cross-vendor communication, and the interfaces are very expensive and they're creating a real barrier. So I want to make sure as you move through the workgroup discussion that you have very specific statements about those standards, and if you could speak to those.

Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO

Yes. I think that's a great point to emphasize. The thought of the workgroup was that the 10%, 10% is according to the standards that are in the certification NPRM, and that applies regardless of whether it's same vendor-same vendor, or to different vendors. And so what we should do from an enforcement perspective and a monetary perspective is just say that if it's same vendor to same vendor you have to do it according to that standard just like if it was same vendor to different vendor. And if there was a concern about not being able to enforce that or monitor it, that's a separate question, but that in terms of the requirement that creates the same incentive for that vendor, whether they're sending it to their own system in a different unaffiliated organization or sending it to another system.

Gayle Harrell - Florida - House of Representatives

But you have to make it very clear that they can communicate directly and that the standards are equal for communicating with a different vendor, that there is that ability to do that.

Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO

Regardless of who they're communicating with they would have to do it according to the standards specified in the certification NPRM.

Gayle Harrell – Florida – House of Representatives

Thank you.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Farzad, do you have a comment on that?

Farzad Mostashari - National Coordinator for Health Information Technology

Micky, the NPRM talked about as part of the rationale for the required cross-vendor requirement that if a provider and vendor could meet the 10% threshold just within a vendor, that this could make the walled gardens that Larry talked about be a scenario where potentially a significant number of providers could meet the requirement but never be actually exchanging information outside of a given vendor context. And what I'm hearing from you, as well as from the Meaningful Use Workgroup, was let's have certification take care of that. Did the IE Workgroup have any thoughts in terms of how it could be done so that the systems are not just technically capable of exchanging information across vendors, but that they actually do follow through on that, both in terms of standards but also business practices?

Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO

We did have a little conversation about that. We didn't get into the area of business practices to the extent that we were saying anything about who was exchanging with whom. So the idea is whoever is exchanging with others, now how they decided who they're going to exchange with is a function of the business, it's a function of the patient patterns and all of that, and so this shouldn't be trying to dictate that or trying to change that, and again we didn't say that specifically but I think that was an implicit assumption of the conversation. That said, I think the idea was that regardless of which platform you're on, if you're sending or receiving to an unaffiliated organization, whatever platform they're on, by whatever ways we are going to monitor and enforce the use of that set of standards, that it should be independent of what platform that other organization is on, that if I'm sending eClinicalWorks to eClinicalWorks to Allscripts, let's say, that there shouldn't be any difference in the diligence that we apply to testing and enforcing monitoring, that they do that, or the standards they require of them to make that exchange.

I think that one of the converse arguments was that, in that scenario that I just described, what you do is if you say that eClinicalWorks to eClinicalWorks doesn't count and eClinicalWorks to Allscripts does count, that what you could end up with is a situation where the eClinicalWorks, and I'm just picking vendors here and deliberating trying not to pick a vendor, so eClinicalWorks to eClinicalWorks, that they could, if that doesn't count, that they could work on building their own proprietary solution that is deeply integrated into the workflow and that creates an inducement for people to use a proprietary solution and that they would create essentially a second tier, not very deeply integrated solution for the Allscripts exchange. Whereas, if you incent them to say, no, that 10% should count, even for your own platforms, what you've done is you've given them the incentive to say, no, let's just do it one way and ... integrate them.

<u>Farzad Mostashari – National Coordinator for Health Information Technology</u>

I ..., my question is from a policy point of view is there comfort that without the cross-vendor requirement we won't end up in a situation where a significant number of providers are not actually exchanging information outside of their vendor boundary.

Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO

Again, I think that the conversation was framed more as they're going to exchange with who they need to exchange with for a patient care perspective and for a business perspective independent of what platform

they're on. So you should create the standards and enforce the standards for the platforms that they're on regardless of who they're exchanging with in terms of vendor to vendor.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Judy, last question?

Judy Faulkner – Epic Systems – Founder

I want to go back to the registries for a minute. I think that there's a big difference between registries such as immunizations and advanced directives, which are more like repositories, and the registries from the associations, and I just wanted to make sure that as both meaningful use and interoperability work on these that you keep in mind that when you work with some of the associations sometimes they have significant fees, such as a percentage of the application, and if the application, let's just pick cardiology, is cardiology, or if the application is the whole EMR, those could be two very different fees. But still it is a percent of the application, whatever that is, so I think we have to be careful if we require these that we know what financial burden is on there, and then in addition I've seen some of the contracts that put a lot of restrictions on the data that is collected and that you can't send that same data anywhere else, so then that, again, I think if we as an organization making up these rules make up rules that we can't send the data anywhere else, we are really being counterproductive to trying to help patients get better, so just to be on the alert for that as we turn this into rules.

Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO

Yes, and we didn't see it as being within our workgroup's purview to decide which are qualified registries or not, but just pointed out that that degree of specificity is needed and it's just not there right now.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Okay, very good. Thank you very much, Micky. These are great conversations.

Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO

Thank you.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Let's see, so we're 15 behind. Now actually Larry had asked for 10 minutes and ... 25, so I was hoping that we were going to cover the 15 in that way, and Marc is saying the same thing. It's impractical to have lunch in 30 minutes when you're trying to eat somewhere, so we'll have the 45 minutes and resume at 1:15, please.

(Lunch break being taken.)

Mary Jo Deering - Office of the National Coordinator

All right, everybody. Operator, would you open the lines for public comment? Pardon me, operator, would you open the lines?

W

(Inaudible.)

M

(Inaudible.)

Mary Jo Deering - Office of the National Coordinator

Latanya, are you there?

Operator

The lines are open.

Mary Jo Deering - Office of the National Coordinator

Oh, good. Thank you very much, operator. Thank you very much, Paul.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Thank you, and welcome back to our second half. We're going to start out with the Privacy and Security Tiger Team, we'll go on to the Quality Measures Workgroup, and then finish with the Certification Adoption Workgroup prior to public comment. Take it away, Deven and Paul.

Paul Egerman - Software Entrepreneur

Thank you, Dr. Tang. I'm Paul Egerman with Deven McGraw. I'm going to walk you very quickly through our evaluation so far of the NPRM and one other issue. This is a list of our Tiger Team members. It's actually been very nice to bring the group back together. We had a hiatus when we weren't meeting, having, I guess, felt that we completely solved all privacy and security issues, but having had a brief hiatus we are back meeting again to talk about a number of issues. Today what we're going to do is actually review more than one topic. Deven's going to talk about new ONC guidance to state HIE grantees that's very interesting, that actually builds on this Policy Committee's recommendations, and then we are going to review the treatment of the committee's privacy and security recommendations in the proposed rules and begin a discussion on the recommendations for Stage 2. What I can tell you just very briefly before Deven starts is we had, over the last month and perhaps years we had spirited discussions on a number of topics that were very important in terms of privacy and security, and it's really encouraging to see how much of that got into the NPRM.

Deven McGraw - Center for Democracy & Technology - Director

Yes. And actually on that score what we want to do to start this discussion is to actually let you know that the hard work that both the Tiger Team did and the Policy Committee did over that initial Tiger Team summer where we considered, in August of 2010, a number of recommendations related to privacy and security, including encouraging the adoption of policies to adopt the full complement of fair information practices, as well as an approach that could be used to resolve the issue of consent. And there was guidance that was issued by the Office of the National Coordinator for Health IT to the state grantees that really follows on these recommendations and incorporates them to a very significant degree, asking the grantees to develop policies that address each of the fair information processes that are identified in ONC's articulation of them, the Nationwide, oh, I never get this name right, but you know what I'm talking about, Nationwide Data Sharing Principles, it has a long name, but it's basically the Fair Information Practice Principles and also it requires the state grantees to address these to submit those policies to ONC. And it also recognizes that the architecture of how you do HIE matters with respect to the policies that you need to address, including the issue of consent and the distinction that you may recall that we made between Direct and Exchange and the type of HIE where data is either centralized or aggregated or collected in the middle.

So the link is on the site. I encourage you, if this is the topic that you want to hear more about, to take a look, but we want to take a moment to bring this to your attention because it's not only in meaningful use and certification do our recommendations get potentially taken into consideration and adopted, and I was, myself, incredibly pleased to see this and we should pass that along.

With that, now let's move to the proposed rule. For those of you who don't remember, we issued recommendations on a number of topics that were adopted by this committee, including the requirement to do a security risk assessment and address encryption of data at rest for Stage 2, and a requirement that certified EHR technology have the capability to support amendments, particularly those requested by the patient. We had a number of recommendations, both on the policy and certification side with respect to patient portals, in other words, the view, download and transmit functionality that's now in Stage 2. We had a number of recommendations on patient matching. The ones that were most relevant to meaningful use and certification involved a recommendation regarding standardized formats for demographic data fields and address normalization. We had some recommendations addressing certification of EHR technology for ePrescribing of controlled substances, and to be able to enable providers to comply with the DEA rules there, digital certificates to support the exchange of data among provider entities, and then certification of EHR modules for the Privacy and Security certification criteria. So it's a big chunk of stuff, and as Paul said, a lot of it got adopted. The recommendation that a security risk assessment and

specifically attesting to addressing encryption of data at rest was included in the proposed meaningful use Stage 2 rule. With respect to the certification rule there are provisions regarding the capability of EHR technology to make amendments and to append information that might be provided by the patient and/or a rebuttal consistent with the HIPAA privacy rule obligations when patients request amendments to health data. Similarly, on the patient portal side we made a recommendation that certified EHRs demonstrate the capability for patients to be able to access an audit log of access in the portal, and that was incorporated as well.

There are a few of our recommendations that we're not quite sure if they got addressed, in part because they're not expressly adopted in the way that the above recommendations were, but they may, in fact, be honored, our recommendations be honored in other standards, such as the use of the consolidated CDA for care transition, summary of care document, and the transport standards may in fact essentially have elements incorporated in them that get at the spirit of what we recommended. And we're still really trying to investigate this and we're doing a lot of work with the Standards Committee Privacy and Security Workgroups, and many of these issues are a mix of both policy and technical. So on that list of not sure is data provenance for data that is viewed by patients in portals, on the patient matching side the standardized formats for the demographic data, and the fields for when data is missing and where there's a standard response for that, and then the use of digital certificates or some other form of entity authentication that provides a high degree of assurance that we asked for in the Policy Committee.

And then not adopted, either by silence or by express non-adoption, in either of the proposed rules is the recommendation on the capability of EHR technology to be able to transmit amendments and potentially appended data if there's a dispute about a patient requested amendment to other providers by Stage 3. Now yes, this was a Stage 2 rule, but I think, as you'll see, what we may be recommending is a signal that this be in Stage 3 because it's pretty important. Patient portals, we had some recommendations regarding the testing of EHR technology and a specific requirement on secure download authentication and an automatic mechanism to block programmatic or unauthorized attacks, the recommendation regarding EHR modules being required to meet all of the privacy and security functionalities in the certification rule, ePrescribing controlled substances, testing EHR technology for the use of digital certificates. And then on the patient matching side, the address, we had a suggestion to consider USPS normalization for addresses for demographic data that wasn't addressed, and then again if you assume that the header of the CCDA has the demographic elements in it that satisfy our desire to create some standardization of demographic data fields to improve patient matching, they're not required necessarily to be tested as part of certification, and we'll go into that in a little bit more detail.

We've gotten through some of this already, and most of what we've gotten through is an agreement that, yes, we should, in fact, be thankful for what we were able to get and to comment specifically and favorably on the things that we recommended that were, in fact, included in the proposed rule, such as the security risk assessment and attestation of addressing and encryption of data at rest, the certification requirement regarding the capability to make amendments to a patient's health data and be able to append information, and on this issue there was a specific question raised in the proposed certification rule about whether the EHR technology should be required to append information that is supplied by a patient, again, this is with respect to a request and amendment that the provider says, now I'm not going to make that, because I don't agree a patient can actually submit information to essentially dispute that and should that be able to be accepted by certified EHR technology in both free text and scanned formats, and essentially we agree that both formats should be required to be part of certified EHR technology.

We also have gotten to the point where we think that ONC should in fact signal to vendors that by Stage 3 certified EHR technology must be able to demonstrate the capability to transmit amendments plus appended information to other providers to whom that provider feels they need to send the amendment to, either because they're legally required to do so or because they want to. And we want to comment favorably on ONC's proposal to require the patient accessible log in Stage 2 of certification. So in many ways we've gotten through much of some low hanging fruit that was relatively easy to get through and now really what remains is some issues that may be a little bit more difficult to resolve in terms of whether it's worth us recommending to the Policy Committee about whether we should continue to press for what

we pressed for initially in our recommendations or whether in fact new information has come to light that we were not aware of when we made the recommendations that make less sense for us to continue to press it, or maybe to press it in a different way, or to recommend something different, assuming that that's a comment that we could make consistent with the fact that this is the proposed rule and we're moving to final rule stage and the ability to get new stuff in during a comment period is limited.

We are in further discussion on these issues and would be very eager to get feedback from the Policy Committee about them, and again, we're trying to work very closely with our standards analog so that we are as consistent as we possibly can be with the recommendations that come forth on these proposed rules. And on the issue of the view, download, and transmit capability on portals, again, we had recommendations initially where we wanted to have the certified EHR technology tested to be able to authenticate patients and to, when the download functionality or the transmit functionality, quite frankly, is used, that that be done in a secure way. And here ONC specifically responded that these are implementations that are quite commonplace and ubiquitous and therefore we don't really need to test for them in certification, and so this is really something that we need to consider because obviously certification is just one regulatory tool.

You also have the issue of HIPAA security rule compliance and the need for providers to in fact assess what their security vulnerabilities are and to deploy both policies and technologies in order to meet those needs, and not all of them necessarily need to, or should be part of certification. On the other hand, we certainly want providers to be able to rely, to a certain degree, on the certification process to give them a system that at least gives them the basic tools that they might need in order to support their compliance, both with meaningful use rules but also potentially with the security rule. I think it's a bit of a delicate dance. Obviously there are a number of things we're going to try to take into consideration in terms of bringing things back to you in May that we might recommend be part of the Policy Committee's comments on the rules.

I think maybe I'll just try to summarize this really quickly since we don't have a lot of time, again, the data provenance issue is another one that we are trying to tee up the capability to detect and block programmatic unauthorized user attacks. This is actually one where our standards analog disagreed with our recommendation and said basically because this is really an authentication issue and their view were that there were other approaches to identity and authentication and making sure that it's effective that would work better than this particular approach and that we shouldn't require this in certification. So we'll be working that through.

You also may recall that we had a recommendation that wasn't pointed at either the Meaningful Use rule or the certification rule regarding guidance for providers to be transparent with patients about the potential risks of the view, download, and now transmit functionality, and this was mentioned briefly in the text that came with the proposed rule, but I think what we might offer you in terms of a recommendation is, again, probably not aimed at either rule, because the initial recommendation wasn't, but to say this is going to take effect in 2014 for a number of providers and they need to be ready, so what's the dissemination strategy, how are we going to make sure that essentially providers and patients are ready for this when it comes time to do that.

On the EHR module side, this is tricky. In Stage 1 of certification modules EHR modules needed to meet each of the security functionalities that are required for certification for a complete EHR. They needed to meet them unless they could demonstrate that it was impracticable for them to do so basically, and that was actually a recommendation that came from the larger privacy and security working group that the Policy Committee had endorsed in Stage 1. We didn't, as a Tiger Team, make any specific comments on this issue for Stage 2, but for those of you who have read the certification rule a number of vendors of EHR modules were quite concerned about this requirement and its impracticability and asked for it to be removed in Stage 2, and it was.

EHR modules don't have to demonstrate the functionalities for the privacy and security requirements for certification when they get certified as individual EHR modules. However, there is now a new concept in certification called a base EHR, which is all of the basic functionalities that any provider needs in order to

meet meaningful use, and you can meet that base EHR either through a complete EHR or through a collection of modules. And the base EHR does in fact have to address the privacy and security functionalities, and so the remaining question for us, and we're working this through with standards as well, is whether if you've got an EHR module that's not part of the base and isn't required to be certified for any of the security functionalities is that going to leave a vulnerability in some way, shape, or form, and more specifically does that mean that providers who purchase that module are left without sufficient guarantees that it's got the capability for them to address the security requirements that they will have to meet as part of the HIPAA security rule if in fact there's electronic protected health information in that module. So, again, it's a tricky issue and it's a very technical one, which is all the more reason why I'm grateful that we have technical folks on our group and we're trying to interface with our analog on the standards side. Paul, you gave me a look. Did I miss something else?

Paul Egerman - Software Entrepreneur

Yes, you've got to -

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Okay, he keeps me honest on the technology side, among many other people on the Tiger Team who do that. On the ePrescribing of controlled substances issue, really what we're examining here is whether we should, again, recommend that the certified EHR technology in Stage 2 be required to be certified for the capability for providers to meet the enhanced authentication requirements that are part of the interim DEA rules, and again, it's way too premature for us to put a recommendation in front of you on that. We're really working very hard, both with ONC staff as well as with our own membership and others, to figure out what would be the right recommendation to make here.

Similarly, on the digital certificate side, again, we had a recommendation that entities have entity level digital certificates at a high degree of assurance to enable exchange, and what that meant for certification was only that the EHR technology be tested for the ability to recognize and use those digital certificates. And this is one of those ones where we're not quite sure, this may actually, at least conceptually have been addressed in the transport standards that were selected, and Farzad is nodding, so maybe you won't hear from us again on this one, other than to tell you we got a happy resolution on this and took a victory dance on it.

Then on the patient matching side, again, we're working on looking into whether the demographic data fields that are required to be in the CCDA, including what are called "null flavors" for missing data, whether they satisfy our recommendations regarding the standardization of demographic data fields. And in particular we said that the certification criteria ought to test that appropriate transactions are sent and received with the correct data formats and that data entry sequences exist to reject incorrectly entered values. And I literally had to read that word-for-word because this is definitely a technical process that I'm not sure that I fully grasp, but the concept here is that the quality of the data and the standardization on the demographic side is one of the things that was recommended to us to try to resolve in order to improve patient matching accuracy. It's not the magic fix. It's not the be-all and end-all. But in terms of having data be able to be matchable from one record system to another when a CCDA is passed from one to another is quite important from a matching standpoint, and in fact ONC did ask for comment on whether the EHR technology should itself be able to perform and be tested to be able to perform matching between the patient that's in the EHR technology of the recipient and the summary of care document that's been sent and that is about to be incorporated, and we just really haven't had any time at all on our previous Tiger Team calls to explore how we would answer this question if we think we even have the capability to do so.

That's it. We gave you a lot of material because there are backup slides with a lot more detail on what exactly our recommendations were previously, what we saw in either proposed rule that may or may not address it, and some sort of straw recommendations that Paul and I, and working with Joy Pritts and the MITRE staff, that we are grateful to have, teeing up some potential recommendations. But we have a pretty long way to go and we're trying to do a lot of stuff off line too so that we can streamline our discussions, but it would be great – Paul, did I miss anything?

Paul Egerman - Software Entrepreneur

It was great.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

When you only give us half an hour it's harder for us to do our usual back-and-forth show, so we want more time next time.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

All right, open for comments, questions? Larry?

Larry Wolf - Kindred Healthcare - Senior Consulting Architect

Thank you, a breathtaking run through the stuff. I was concerned we would do all the backup slides, so thank you for stopping. You mentioned a couple of times data provenance, and I think as we look at information exchange and collaborative teams working together that becomes more and more important. And historically the record systems have done a great job of saying who entered the information and when it was put in and tracking it and edits and all that stuff, but the assumption has been it came from this provider organization in this electronic record and the notion that we're now bringing in data. At the beginning stages a lot of people are sort of walling it off, they're saying, okay, I got this document from outside and it's in the documents from outside section of my medical record, and so you know where it came from because that's in the metadata around it, and you go somewhere separate to look at it, but as we start to integrate the data in more, whether we're using it in a reconciliation process or we say I'm going to bulk accept the lab results that are in this document so that they now show up in my flow sheets and I can see them, they show up in my graphs, and then I have a question about that data point, how do I know where the data point came from. So it's the next tier of does the EHR actually track the history of the data elements as it starts to pull them out of the documents.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

The CCDA has data provenance in the header, I think because our recommendation on that issue was more specific to the portal and whether patients would be able to see that, that's the piece that we're exploring, which is just a tiny nugget of the point that you made and probably is one of those that we will likely be able to resolve with a little more exploration of the facts, yes.

Larry Wolf - Kindred Healthcare - Senior Consulting Architect

I feel like this is probably not a crisis thing that we need to address in Stage 2, but it seems like as we look to actually having broad adoption and broad exchange, that by Stage 3 we're going to be actually talking about needing to surface as the data gets integrated in, maintaining the provenance as it comes in beyond the boundary.

<u>Paul Egerman – Software Entrepreneur</u>

Yes, good point.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Right.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Gayle?

Gayle Harrell – Florida – House of Representatives

Thank you so much, and I just want to say thank you so much to Paul and Deven for all the hard work that they have done with the Tiger Team. It's just been incredible. I'm now back on task, I'll be back with you ... session is over. But I do want to make a couple of comments on two things. First of all, I want to really address the digital certificates. I think those are critical, and the testing of those is absolutely critical. So as we get more in the committee into discussions on it, I think that's something that's got to be really, really looked at, and if you're not going to include digital certificates and authentication how are you going to do it? There has to be another answer. That's not the right answer.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Right. I think that's why the exploration of the transport standards and what are those authentication protocols that are embedded in those transport standards will really help us resolve those issues.

Gayle Harrell – Florida – House of Representatives

Right, and that's going to be critical because if you want the public to really embrace what we are doing you get to the security standards and making sure that they know everything is appropriately done, they have to have proper authentication, and this is absolutely critical. Along that same line the second thing I want to really look at is those EHR modules, and when you get down to really the weakest link in a chain is the strength of the chain, so if you have modules that don't meet standards, if you're looking at a base EHR, how do we know that that module, that the security is really there in that module and does it really integrate into that base EHR, big questions. And again, public perception becomes reality, and if they don't see that the entire record is secure and the information is kept private, we will lose the confidence of the public. So I think those are two very, very important issues that if we need to push back on the NPRM we need to do it.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Anything else? Terry?

<u>Terry Cullen - Director, Health Informatics, Veterans Health Administration</u>

I have two comments, one is related to ePrescribing. I'm sure you're aware that every state, or most states, now have their own narcotic or controlled substance prescribing, which is a pull, I have to assign and I have to get my new ... and verify code, I have to be verified by the state, and it doesn't interact at all with the electronic health record. So I think as we move forward knowing the issues surrounding controlled substances prescribing and what the states are doing, it goes back to this: what do we do with all these registries? This is a really critical registry. It's being fed predominantly by the pharmacy benefits, as well as some prescribers are putting data in there, but a huge potential benefit. So I think if we look at ePrescribing of controlled substances we really should be paying some attention to that. And secondly, and this is just a general comment and it goes back to the disparity discussion about homeless and homeless demographics, so when we talk about address we're assuming everybody has an address, and there's been a lot of work there, the Homeless Coalition of America has a pretty standard data collection tool that should be done for people that are homeless, and this is clearly an issue in the Veterans Administration as we strive to eliminate homelessness, so I would just urge us to be attentive to that work that's been done because I don't think an SDO is going to pick that up. That's a population that doesn't have a voice and we need to figure out what to do.

Paul Egerman - Software Entrepreneur

Good point, thank you.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Yes, thank you. I wrote that down.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Anything else? Thank you and we'll try to honor your request for more time in the future.

Deven McGraw - Center for Democracy & Technology - Director

No, I get it.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

No, no, which is a good lead-in for -

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

We like to do our back-and-forth.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

That's right.

<u>Deven McGraw – Center for Democracy & Technology – Director</u> It takes time.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO Thanks. Deven and Paul.

<u>Deven McGraw – Center for Democracy & Technology – Director</u> Thank you.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

As David Lansky gets ready to give his presentation I think we will start earlier, because we're up against a timeline we do need to get it submitted following the next meeting, so we'll plan on starting the next meeting early, like 9:00. David Lansky's going to report on the Quality Measures Workgroup.

<u>David Lansky – Pacific Business Group on Health – President & CEO</u>

Thank you, Paul. We have had a very vigorous discussion over the last month about the proposed rule, and I want to thank especially Kevin Larson and Josh for helping to navigate us through this complexity. You'll see here a list of the workgroup members. This group has been gradually repopulated, so it has a lot of expertise and a lot of diversity of experience, which has been very valuable in our discussions, so I definitely want to thank all of them for making time to try to work through some of this. As you've all seen in the rule, there are a couple hundred measures in there and we have not tried as a group to go through all the measures and evaluate them one by one, but instead we've tried to keep our discussion at a level where we can respond to the request for comments that CMS specifically called out in the proposed rule. And rather than try to organize it that way for today's discussion I thought I would just group them into three or four categories of where I think the group has come out in a couple of areas where we don't have total agreement of how we might recommend that this group comment.

There are three areas in particular that keep surfacing in our discussion. One is this area of alignment across the many programs, and everyone is interested in seeing more alignment and less burden where possible. Second is what I'll call the vendor platform design, which is really the challenge of whether the vendors are able to respond to the continuing changes in the quality measures that are being sought. And third is basically how are we doing. We all agreed a couple of years ago that Stage 3 is the time when we would like to have outcomes be something we are evaluating our program on, and that, and Paul, as you articulated it, over these three or four years we would see a migration of the emphasis less on prescribing functionality and more on evaluating health outcomes, so the question as we look at Stage 2 is are we making appropriate progress toward the ability to do that two or three years from now, and so I'll comment on where we seem to be on that score. Then there are several other important topics, like group reporting, which will surface in my other comments

Maybe I'll do as Paul did this morning and go through these pretty quickly and then we can come back and take each of these one by one for discussion. On the alignment topic, we did hear from some people in the workgroup that Meaningful Use Stage 1 has been challenging, especially for smaller practices trying to generate the quality measures, they may not have the capability or experience or expertise to do that, so they're certainly relying on the vendors, and this will tee up this larger question of the vendor platforms and their ability to generate more quality measures. If you looked at the proposed rule, there are now 125 or so potential measures available, that may change in the final rule but at the moment there are 125 published for EPs and I think 60-some for hospitals, so you can imagine that would imply that vendors would have to be coding or creating the capability for now maybe 200 measures to be generated from their EHR product, so then in turn the users would have to be capable of producing some of those measures and looking at them and making some good use from them. So that's potentially quite burdensome and we want to think about ways of making sure we're aligning that work with other important outputs that they have to generate.

The second point here is that while we all support alignment, especially to reduce burden, we don't want it to become a lower common denominator alignment, we don't want to take the lowest standard of all the

programs and make that what we align to, so especially this particular program, which is meant to push us into a new world of capabilities with electronic health records and HIE, naturally the measures that are e-Enabled for this program may not map to the measures that made sense for previous programs, the legacy programs that the federal government may still be operating. So I think there's tension between how do we have the benefit of alignment but keep moving the process forward with the new technologies that we're all supportive of. So, for example, while we could say that if you pass on the traditional PQRS requirements we will deem you to be a meaningful user if you submit your data using a certified EHR, alternatively, we could say, no, if you meet the new meaningful use criteria we deem you to be a PQRS user, and that would then push you into some capabilities that we've all agreed to here, like the six domains that have to be covered and so on.

Thirdly, we just want to keep an eye on the fact that the federal programs are all trying to align in ways that support payment for value in one form or another, the hospital value payment, physician value modifier, ACOs, episode, and so on. We want the information platform that we're all using in the clinical environment to support the data that will be used to support those programs, so we want the alignment of the EHR quality measurement to also map to these new value promoting programs in the government.

The second big topic is the vendor platform, which is really, certainly I don't know a lot about where we are with capabilities, and maybe we can talk about it here, but I think there's a great concern that the vendors' approach to quality measurement in Stage 1 was to hard code each of the measures and that we've heard a lot of good arguments why that's necessary in terms of the idiosyncrasies of workflow and the need to get this into being a turnkey situation. Nonetheless, it's hard to see the future from here. How do we get to having all the vendors hard code hundreds of measures knowing that each individual customer might only pick 12 or 11 or some number to actually execute for their own environment, the vendor's going to have to program all of them, and that will increasingly become a bottleneck for new program requirements that CMS or somebody else might come up with for a measure they want to use for paying for value or some other kind of program. So how do we not allow the technology to become the bottleneck of improving value promotion in healthcare?

One question is if we can improve the vendor platform capability it will make it more capable for the providers to use a variety of measures they find of interest to generate quality improvement strategies internally, they'll be able to drill down and utilize the data more robustly if the platforms are flexible. One argument that has been made is that if we do keep the, what is called in the rule "Option 1A," which is to report 11 out of 125 proposed measures, that would reduce the likelihood of continuing to hard code, that the vendors would have to figure out a way to create a flexible, table driven or plug-and-play driven model for quality measurement reporting, so that's been one argument in favor of 1A. And we'll come back to that 1A business in a minute.

Thirdly, I think there's a lot of support in the committee for the proposed link that was in the rule between the clinical decision support choices that the meaningful user might make and the quality measures they choose to report. Coupling these things together as a suggestion is a really great idea, and again, it's a suggestion to the vendors to build that interlocking capability of generating the quality measures and tying it to the clinical decision support functionality as something which makes that easy for users to do would be a really powerful enhancement of our capabilities in the EHR world.

Lastly, progress toward the outcome goal that we've talked about, so the workgroup clearly reinforced, restated its support, as this committee has, for the six domains to report, have EPs and hospitals report across those six domains and not just get locked into one category or another. In Option 1A, which does require the EPs to pick at least one measure from each of the domains, that is something we supported probably for that reason. It's advantageous to keep everyone's attention on satisfying at least one measure in each of the domains. I mentioned the link between quality measurement and clinical decision support, and while there was support for alignment and for having, as there is in the published rule and the federal register, there's a nice table that illustrates how each measure is used by other programs like PQRS and so on, I think the committee asked for even more precision about showing that the proposed measures are applicable to multiple programs, and so we'll be able to see, and the users will be able to see, how their picks are efficient in satisfying the requirements for different programs.

We talked about the need to satisfy the multiple six reporting domains, but alas, when we look at what's actually available in the measures pipeline to satisfy each of those six domains, it's not great, and I'll show you an example in just a minute. Next to the last there, the data elements and the data types needed for Stage 3, so we've certainly talked here about a number of goals we have for longitudinal measures for health status and functional measures, for patient experience measures that would be available in Stage 3, and a strong emphasis on outcomes, including connecting data from multiple sources, like readmission rates or complication rates occurring post-discharge, and whether we now have in the Stage 2 certification requirements the ability to capture all of the data we'll need for Stage 3 is not clear. We haven't done a deep analysis of that, but it's an important question.

And then finally, some of the measures that we think conceptually are important have been proposed as what we call check the box measures, meaning, yes, I did an assessment of functional status but I'm not actually capturing the result and able to use the result for any analytic purposes or care management purposes, it's just I did it. And we in general are trying to discourage quality measures that are check the box.

Let me give you one illustration of where we are on this trajectory of the measures pipeline. These are the six categories of measures, and on the first column you see the number of measures that are in the rule in each of the six columns, and these were labeled by CMS in the rules, it's their categorization. You see there are obviously still a great number in the clinical process, many of them yield PQRS measures, and then we have a decent smattering in each of the categories. Care coordination, unfortunately is a weaker one with only seven proposed measures for EPs. The next column is the number of concepts that the Tiger Team said they thought we should be working toward, and in our letter last August from this committee we endorsed the proposed measure concept. So in respect this committee has been on the record saying, yes, we want to achieve the things in column two there, the 10 concepts in clinical appropriateness and efficiency and so on.

The number of those measure concepts that the Tiger Team and we endorsed in August that actually made it into the rule as an available Stage 2 measure is in the third column, and you see it's only two or three in each of the five categories that are the more challenging ones for us that are not the traditional measures. So the good news is we do have now a dashboard, a framework that covers a lot of important ground and we do have some measures in each of them and we are now asking providers to address their quality measures in each of these categories. So that's all good, we are on the right path. But the availability of the measures is pretty thin.

So just to drill down a little bit on the care coordination example, these are the seven measures that are in the proposed rule, and as you see, I actually did the numbers on how big the denominators are in the U.S. population of each of these conditions and it's really small. We're going to have very, very few providers, mostly specialists in certain areas, who are going to have cases that would make them choose one of these seven measures, except for the last one, closing the referral loop. So even in the care coordination area we've chosen a set of measures that are available, I don't want to say we've chosen, what's available to NQS and CMS for publication in this purpose is a very thin array, it doesn't apply to very many physicians, we're not going to see a lot of meaningful quality improvement and measurement around care coordination if this is the best we're able to do for the next two or three years. And I'll also point out, even though there are sevens in both columns of the row up above, those are two different sevens. The priorities that the Tiger Team indicated were these kinds of things, and these were among the seven that the Tiger Team had proposed, and as you see, these are really not addressed in the available measures for Stage 2. So the question is, what are we able to do and how can we as a committee encourage attention to those other four in this example and we could do the same analysis for all the categories, but I thought this one, because care coordination is one actually the workgroup in the last few weeks has really highlighted as a priority that isn't adequately being addressed by the measurement pipeline that we have today.

So I guess the overall assessment is we have the right framework, we feel good about the framework, we want to continue to advocate for it, and now the challenge is how to really accelerate the ability to use this

framework in common care settings and not as esoteric as some of the ones that we have available at this point. Several other important areas were discussed in the workgroup the last few weeks. In general the hospital approach has been generally quite well supported. Except for some additional specifications about denominators and so on the committee has felt very good about the approach to hospital quality measurement that we're now bringing forward.

We've had a very lively debate on the question of whether there should be fewer measures that everyone is asked to report, which is Option 1B in the EP set, versus having more measures available and people choose their own, and essentially the debate is in favor of fewer measures, which is 1B, we're more likely to get reliable, robust measurement and comparable results because everybody's reporting them, and the argument in favor of a larger inventory of measures is that everyone, the specialists can find themselves on there somewhere and they can feel like we're measuring something important to their particular area of work, and I mentioned earlier the ability to improve the platforms by having a larger library of measures to be built in. We did not resolve this issue. There's a difference of opinion in the workgroup, so I don't know that we'll offer a definitive, there was a tilt toward 1A, but there are arguments pro and con.

We had an extended discussion of what criteria we would recommend to CMS if they wish to reduce the length of the list of measures, so CMS specifically said, please tell us how to reduce this list lower than 125 measures, and there's a quite diverse opinion in our workgroup as to what the criteria should be, and I don't know that we'll be able to come to a consensus about what we would recommend to CMS on that. There is agreement that we need tighter specifications and implementation guides so that what is measured is more comparable than what may be coming out of the pipeline today, so tightening up the specs and ensuring that they're implemented properly is something we felt strongly about.

And lastly on the group reporting option, I think in general we agree that group reporting would be a good way to go. It supports a lot of the values that we all talked about, and Paul talked about this morning. There are, alas, three different options in the proposed rule and it gets a little confusing to track back what each of them really implies, but I would say the consensus in our workgroup was we are concerned if we are simply taking a bunch of eligible professionals sharing a common tax ID and having them report quality measures across a bunch of docs, and we don't really know who this is about and which of the doctors are being addressed and which are not being addressed, especially because the quality measures are themselves specialized and esoteric. So it may just simply be that we need CMS to be very careful in designing the group reporting option to not lose the ability to meaningfully measure physician performance or the whole group's performance.

One solution to that would be to say that for group reporting purposes using option 1B, that is, all the physicians in the group are reporting the core set of generally primary care oriented measures, makes sense for a group for whom that makes sense. That's the nature of their practice. The group reporting, the PQRS group reporting option has, I think, 29 measures in 2012, so it's a more robust set of measures anyway, and that's a place where that alignment would be very natural. If you're in the PQRS group reporting option reporting 29 measures using certified EHR, that's a very close mapping to what we're looking for in the current Option 1A approach that we have here, so that may be a good solution.

Let me stop there with the overview of a lot of complicated material, and I'll go back to the beginning ... any comments. Thank you, Paul.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Thank you, David. Comments, questions?

Farzad Mostashari - National Coordinator for Health Information Technology

David, the 1A and 1B, and I'm not sure if folks need a little primer on those two options, and as you do so if you could comment, please, on the impact potentially to Option 1B of if there are 11 core required proposed across the domains but many of those are the exact ones that, as you pointed out, development is occurring now and others who may not be, for one reason or another, may end up being not in the final rule, whether they haven't been tested sufficiently, whether they're new measures in the terms of the availability of the measure or in terms of comments, so what would be the impact if it ends up

that there's only 6 or 5 or 4 of the 11 that are put in as core and required, if that drops back to 4 or 5 or 6, so 6 core and then pick 6 from the menu, does that change your perception of that as being something ... in terms of recommendations?

<u>David Lansky – Pacific Business Group on Health – President & CEO</u>

I can't speak for the workgroup's opinion on that scenario.

Farzad Mostashari – National Coordinator for Health Information Technology

Was that discussed?

David Lansky - Pacific Business Group on Health - President & CEO

No, we didn't discuss a hybrid or a consolidation of the approach. I think the themes that I summarized from both approaches, if there's a way to address those themes with a more elegant combination, that that might be appealing to the workgroup. The ideal of having many physicians find themselves somewhere on the chart and feel like these measures are relevant to their practice and they want to improve performance on those measures is certainly a good thing, and that's in favor of the long list. The idea of having a core set of measures which drives performance on high priority conditions and permits comparability and robustness of measurement is also very attractive. So if we can get both of those, maybe that's a better solution. But the group didn't really think that through, and maybe we ought to in a a few weeks, before the final comments maybe that's something we should ask the group to come back to if you think there's a discussion that would consider that kind of a blend we could certainly ask the workgroup to ponder that before the May deadline.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Christine?

Christine Bechtel - National Partnership for Women & Families - VP

Thanks, David. It was really helpful. I want to come back to the alignment thing, and I've raised this in a couple of meetings, but I agree with you about the, I guess I should say I agree with the workgroup about the direction of the alignment, that it's a two-fer, if you can successfully meet meaningful use quality measured requirements then you've got PQRS credit. But I don't think it should be the other way around for some of the reasons that you mentioned. But it's also not clear to me, given the fact that right now PQRS only requires physicians to report three measures, and we all know the problems with so many of the measures in PQRS, but it also allows you to do reporting on a family of measures, which I think is a nice approach, but the denominator for that approach, if you take it, is only 30 patients.

So I think that the purpose and the origins of PQRS are sufficiently different from what we're trying to do with meaningful use, and that if when we look at the landscape of new models of care and the advancements we need to make, I feel like we keep getting stuck in looking at meaningful use through the lens of the current quality measurement enterprise and yet we've all been pinning a lot of hopes and aspirations on health IT to really advance that enterprise. But we seem to still be stuck in that construct, so with respect to some of the new potential measures that are being developed, or I think actually in most cases, Farzad, it's more they're being adapted, they were existing measures that I think are being adapted for potential use in Stage 2, like functional status improvement, where we had a functional status measure, but I think that what I would be very interested in understanding would be the potential for the meaningful use program in those cases where there is some new measure, either development or adaptation, to be a proving ground for those measures, because we've got to do that somewhere and it strikes me that we can't look at meaningful use as a performance program because it's not. You just have to report the measure. It doesn't matter how bad the performance is on the measure or how good, it's just a simple reporting mechanism. So I'd really like to think about MU as a real proving ground for much more advanced measures so that we get the capacity out and developed for the kind of measures that we're really hoping to see in the future.

Farzad Mostashari - National Coordinator for Health Information Technology

As I said, I think it's a really thought provoking comment. The measures that the Tiger Team recommended, and they did mostly recommend the gap areas where there were not really existing

measures, many of those that are the broad, the parsimonious, closing the referral loop, as an example, there was not a measure that would be adapted for that, medical management of medications ... adverse drug events, we're looking to see if any could be adapted but it's looking, actually, like pretty new ground is being broken on that, a lot of the patient experience or functional status similarly, so some of the ones that actually are the ones, in a way, most suitable, whether you give a referral, get a referral, closing the referral loop is relevant to you, right, that was the idea there, as opposed to some of the more targeted small bore ones, those are the very measures that are under development right now. And taken with one view, one would say those might be the ones most at risk of falling off because if the development is delayed, if the testing is delayed or whatever, those may be the ones that have the least of a track record.

But I think what you're proposing is a little bit of a different view of meaningful use and what's important for meaningful use, putting a greater emphasis on health IT ... quality measures built for EHRs and laying the foundation for future cycles of other programs' payment cycles and the things adopting those. So I think it's important as the Policy Committee and the Meaningful Use and the Quality Measures Workgroup makes that difficult conversations about what are the measures that should be kept and what are the measures that could be gone, and one of the axes I'm sure in your thinking is going to be well, how broad-based, how parsimonious, how health IT sensitive, but also how mature a particular measure is, and I think those are values that the group is going to have to assign to each of those, and I think those are some of the important discussions that we're going to be looking to get in the comments.

Christine Bechtel - National Partnership for Women & Families - VP

I think that makes sense. I would say the Tiger Teams that did the work as part of the Quality Measures Workgroup did that in I think it was the fall of 2010, so by the time we get to Stage 2 and final rules, and we're talking about, I think it's about a five year lead time cycle, and it makes me very anxious that we can't quite get something done of value in an HIT world in five years, but what if we were able to take an approach where if the provider chose some of these newer measures to report on, that we either somehow give them extra credit or give them some capacity for being able to say it just didn't work without getting a penalty, if there was some way to incentivize the selection of those measures so that we can really understand, we can foster the work around improving quality for those measures, but if there's a problem in the simple reporting of it you don't get dinged. So something that we can consider to really incentivize, that might be interesting.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Can I just pick up on that? That's a fascinating idea. On the one hand you don't want to promote something for nationwide adoption and use before it's tested. That's the lesson learned from NQF. On the other hand we could use the CMMI kind of approach of saying could we give at least credit for some number of measures of what's important to you all that you wanted to do anyway, especially if we have EHR platform engine tools to be able to do that, start moving the ball, so not only for measuring but for innovating in terms of how do we pick the things that we're very interested in. It's a little illuminating, your comment about these being actually gap measures. They were developed as normative measures, in other words, what we would like to, and it turns out they're all gap. That's the statement. It's not that we were looking for the gaps. So in a sense meaningful use is driving actually for the eye on the prize, and we might be unnecessarily restrained by what's close, not even close enough but close, and should we start trying to use this program even to go where eventually even CMS wants to go. Presumably we have that latitude, actually, as far as recommendations from policy because it's not prohibited by HITECH.

Christine Bechtel - National Partnership for Women & Families - VP

Right, in fact, I would suggest that HITECH actually enables it because HITECH does talk about improvement in outcomes in some way.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Except that there's a preference for NQF endorsed measures, so that's the only, in a sense, restraint, but that doesn't mean it can't exercise some of its latitude in terms of promotion. So in a sense it would be, again, a hybrid of 1A and 1B, but there's a 1C that has some number that you get credit for showing that you're reporting on and using and it doesn't have to be on the plan yet.

Christine Bechtel - National Partnership for Women & Families - VP

Right. The last thing I'll say is just that I feel like we get so hung up in quality measurement and reporting that we forget that the whole purpose of measurement is actually improvement, so if we get people focusing on the concepts then just don't ding them for not being able to do the technical reporting side, but they've got the data elements in place, they're thinking about the goal here, and they're measuring and improving things that are really relevant to them.

<u>David Lansky – Pacific Business Group on Health – President & CEO</u>

I'll just add in terms of the alignment issue that not only are these concepts good concepts, but most of the payment reforms that are underway for 2015, 2016, and 2017 are focused on achieving the goals of these domains that are the gap areas, and if other CMS and other payers don't have any way to measure performance on those domains there's going to be trouble everywhere. I think EHRs are hopefully one of the tools that will be available to support meaningful improvements in our overall system, and so I think the importance of accelerating this is very high.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

I don't know about the exact order, but I see Neil, Gayle and Terry.

Neil Calman – Institute for Family Health – President & Cofounder

I guess I'm responding to the idea about using meaningful use as a testing ground for these measures. I think we're balancing two different things. To me the most important issue here is to create a platform that people can use so that in the context of their local practices and the things that are going on in their communities, and it might be a community of providers across the country, all of whom practice dermatology, or it could be a geographic community that's got specific health issues, that somehow the tools are available for them to develop measures in a flexible way through the systems without necessarily having to go back to the vendors, to me that's the Holy Grail.

But then if you get to the other side of it, which I hear us talking about, it's like trying to use meaningful use to ... specific measures and perfect them, and to me those two things in some ways are contradictory. And I know that we can potentially do both, but I guess I'm putting in a vote in favor of really trying to maintain the greatest amount of flexibility. And I say that because I think we constantly neglect to think what are we testing the measures for in the future? Are we testing them so that some day they can be used in pay-for-performance? Are we testing them so that someday a provider can pick it out of a list and say I really want to look at that in my practice today? Are we testing it so that we can meet some new government or health reform kind of regulations, so we can report on our UDS data for community health centers or to the Joint Commission or to the newest PCMH reporting requirements?

I don't think we can develop, for all of those reasons, or for public reporting, which is like a whole other thing that people are thinking about, like who's going to find out about all this. Those different callings are not compatible always in terms of both what you would measure, how you would measure it, how you would develop it, so I think we have to rewind to what are we developing this for, maybe it's all of the above, but if it's all of the above then I think we're in a quagmire that's going to sink us. And so I would just say that the flexible platform enables people to develop measures for all of those things and it focuses on what the measures are for rather than what the measures are. And I think that ultimately that's where we should be. I think that's what we have to think in terms of meaningful use, is fewer measures and more specificity around how you create a flexible and usable reporting platform within an electronic health record system.

<u>Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO</u> Gayle?

<u>Gayle Harrell – Florida – House of Representatives</u>

To me this whole issue of quality measures and what you're going to use them for is a very broad question that we have not really looked at why are we doing this? You've got to analyze before you go into the thousand flowers blooming or whatever, we haven't answered the question why? Why are we doing this? What are we measuring, why are we measuring and then what are we going to measure to

achieve the goal we want to achieve? Until you answer that basically you really have so many different proposals, so many different things out there, that you've really got to, and the workgroup needs to have that conversation as to why are we doing this? Are we doing this to achieve meaningful use? Are we doing it to meet PQR requirements here, there, and everywhere? Are we looking to measure for me as a provider what I'm going to do in my population of patients to improve my outcomes? So what's the goal of why you're measuring? What are you going to measure? Why are you measuring? And then what are we going to measure to get to why? So if you do the thousand flowers bloom, then you give more flexibility to allow providers to achieve what they are looking to achieve and if they then can use those measures, to achieve other things for CMS for an ACO requirement or whatever else comes down the road, then you will have the ability to do that. But until you determine why you really have to back up and look at that first. So I don't know that by May you can come to that conclusion and you can really make a recommendation, and this is certainly building towards Stage 3, that it's an ongoing conversation that perhaps this committee needs to be involved in as well.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Can I just put a reminder to this group on how we got here in addressing the questions that you and Neil raised, which is why are we working on which quality measures. Our original purpose was to find exemplar quality measures that would exercise an EHR that would give us the flexibility both to measure and to impact, so the measure is the reporting and the impact is the clinical decision support. That was the original goal and at the same time we wanted to align, and that's how we're piggybacking in a sense, with other initiatives. So that's how we arrived at this place, so we're not so much concerned about what measure to pick as much as not causing re-work, which is the alignment and getting flexible tools in the system we're trying to promote.

Gayle Harrell - Florida - House of Representatives

Certainly the alignment is very critical in not putting more work on providers. That's the last thing they need. And with limited resources it becomes difficult to do because every time you're trying to meet another goal or provide information it's going to cost you money to do that.

M

Can I just say that I don't think you can align because what you're aligning to and what you're perfecting is going to take two years, and by then those measures are gone, because we're on to something else. So PCMH measures are evolving. I just got a notice today in an e-mail that we're all invited to a Webinar to hear about the new UDS measures that are coming out. What are we aligning to? We're aligning to yesterday's PRQI measures, but if we keep aligning we're not aligning to a future vision. I thought that was the most important point that was made, the future vision is really things that we haven't even thought about now, and we need the tools to be able to do measurement and to see how we're doing along those things, and we don't know what those are yet. I think we're going to always be looking backwards if we're not creating the flexibility and the tools we need to be able to constantly refine and look at new things as we're progressing. I would never have thought that anybody was going to ask me how well are we doing communicating with housing providers and home health providers and other people until the health homes came out, and now that's become the most critical part of my day is talking about how we're going to know whether we're actually communicating appropriately with this network of people that a year ago I never thought I was going to be communicating with. So I appreciate the alignment piece, but I don't think that's the answer.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Judy has a relevant comment and then ... Terry.

Terry Cullen - Director, Health Informatics, Veterans Health Administration

I actually wanted to step back a second and go to Stage 1 dialogues we had back there about capabilities to do performance measures. I'm really concerned that we're now having 125 performance measures, because despite what we think the vendors are going to hard code them. At IHS we would have hard coded every one of them so that we had apples to apples and we could say we knew that, which is a tremendous expense and it doesn't get us to where we need to get. So the real issue maybe is capability and what I'm concerned about is that that's not in this dialogue, and it's not in this dialogue because the

pressure, as Neil talked about, is really to report the latest and greatest measurement that may get you a little more money so you're going to do it. But if we want to steer the health IT agenda perhaps what we need to do is take some baby steps and say your ability to calculate measures needs to include this capability that obviously can be tested in certification and at the same time gives us some latitude as we move forward.

The other concern is all the small practices that are going to have to pay their vendor for the new 125 measures, that \$10,000 per measure, and I don't think we're recognizing the incredible financial impact this is going to have on the provider. I think if we get in this quagmire, 125 measures, next time it's going to be 400.

<u>Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO</u> Judy?

Judy Faulkner – Epic Systems – Founder

Two things, one, I think we have to be careful too of the time it's going to add on to the providers, as someone mentioned, but one of the things, osteoporosis post-fracture communication ... may be multiple clicks, so it might be a bit of Secondly, ... also, it's not just ... this is not going where we want to go but if you have the vendor reprogrammed that means that all the things a vendor could have done the first time around to hopefully build better systems get tossed. And thirdly, the question, did you have EHR software developers reviewing this to see whether in fact it makes sense that what is there can be written in a way that can be flexibly done?

David Lansky - Pacific Business Group on Health - President & CEO

I don't know whether that's really a question for CMS or ONC. I don't know what reviews they did prior to publishing the –

<u>Judy Faulkner – Epic Systems – Founder</u>

Because that's going to be essential, if ... developers around this say there's no way but they're hard coded, then they're not hard coding it as an escape from the work they should do. It might just be there is no way.

<u>David Lansky - Pacific Business Group on Health - President & CEO</u>

It gives us the opportunity -

Judy Faulkner – Epic Systems – Founder

... purpose.

David Lansky - Pacific Business Group on Health - President & CEO

... to have a dialogue between some of the vendors and people advocating these measures address this discussion and say what is the platform approach, to Terry's point. Is there a way to specify some capabilities that would cut through this and give us the flexibility Neil and Gayle talked about? And also one of the flexible products could be reportable measures for payment and other purposes but certainly the flexibility at the user end would be built in.

Farzad Mostashari - National Coordinator for Health Information Technology

This does not have to do with the reg so much, but I think our conversation has gone beyond there are 125 proposed measures and which ones do we ..., right? This is a broader conversation, so I'll make a broader statement that echoes what I said to the AMA PCPI meeting last week around quality measurement, which is it's naïve and maybe it was a lesson that we have to learn by doing, but it's naïve to assume that you can just have a platform that will take any measure that was designed for a chart review world and will just calculate it in an EHR. So part of the learning here has been we've got to go upstream in the measure development, measure prioritization and measure development to have quality measures that are built from the ground up to take advantage of the strength of EHRs rather than trying to assume that you can capture every data element that you can in a chart review, because where you end up there is exactly as David said, you end up in a check box somewhere. And, yes, I can calculate any

quality measure you want as long as there's a check box that says is the patient on highly active ... therapy? You can check that, but you have an automated quality measurement, you just added more checks to the doctor's life and instead of it being a chart reviewer who does that on 411 patients, now the doc has to do it on every patient. And that's not going to work. And when we're talking about EHR generated quality measures what we're really talking about is automating quality measurement so that the data that's captured as a routine delivery of care, so that that medication list can generate whether the person's on ... therapy, instead of having a chart reviewer reference a 35 page document that gives you guidelines and says consider the person on ... if they meet these combinations, and that can change all the time and you can't change it based on a two year regulatory cycle when the next medication comes along. So what I think we should not underestimate either the importance of getting to a point where EHRs can serve as a platform, nor the work that it's going to take not only in terms of the technology of the EHRs but also in terms of how quality measures are developed, and the concept of having a quality data model that is actually constrained not to what is possible but what is feasible is an important part of that conversation.

That having been said, it is important for us to start developing those quality measures that are broad, parsimonious, health IT sensitive, built on the best electronic health records that look at longitudinal outcomes and so forth, and currently don't exist. So I don't think it's an excuse to say oh, we're going to work towards the future perfect state where wherever you ... the platform there's no need to worry about the measures are, because we do have to worry about what the measures are because those measures are lacking right now and if we don't get a move on we're not going to have them five years from now, is the sad truth, or four years, or three years from now, because it just takes that long. So I think we have, ... back to the reg, we've got a question in front of us, there are a lot of retooled measures here and there are some de novo measures here, and the Quality Measures Workgroup has got to give recommendations on which ones are important to include and how to balance the lack of testing or maturity or whatever on the part of the EHR measures, versus the lack of maybe meaning on the retool measures. I don't think it's a moot discussion.

<u>Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO</u> Terry?

<u>Terry Cullen - Director, Health Informatics, Veterans Health Administration</u>

I don't think it's a moot discussion either, however, I think it behooves us to not end up with unintentional negative consequences, and we theoretically can go down a rat hole here, with 125 different measures all with different specifications, maybe some tested electronically, maybe not something tested electronically, and no vendor community, because I think what Judy said is really true, a vendor community to help guide us in terms of what is feasible from a software programming perspective and is economically doable and is not going to make people crazy out there. I think there are two different things here and we can't forget that somehow we need to do this step back and I would say the QDM is trying to do that and say this is the capability and your system has to have the capability, and it might be different in Stage 2 and Stage 3, and then if you have this capability here's the measures that you're going to be able to go from, but we have to conjoin them, and the capability model isn't anywhere in meaningful use. But it doesn't say your system has to do A, B, C data fields and ... and be able to calculate to this nth degree and parse by disability or something, some other data field. That's what I'm talking about in terms of ..., what's the equation? And the equation is not in certification.

<u>M</u>

(Inaudible.)

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Okay. I think in your examples, Farzad, I think you mentioned a couple of things that are important to differentiate. One is measurement of things that we're currently capturing, but a lot of the things that you're talking about actually require us to capture new data that we're not capturing, so if people aren't doing disability assessments, they're not going to be able to report them out. If there's no way that people are reporting now at all with their communication with providers, then between providers if they're not reporting that in any way in the communication that takes place, let's say verbally or by phone or

whatever, then you're not going to be able to use an electronic system no matter how sophisticated you think your reporting is to figure out whether osteoporosis reporting was done for somebody post-fracture because they're picking up the phone and calling their friends and telling them I'm sending back this patient who just had a fracture and if they're not reporting that now in any way that conversation, so a lot of these measures are calling out not just new clinical decision supports, but actually beginning to, I guess beginning to call out a whole different set of things that you're asking providers to do with the electronic health record in terms of documentation and other things like that, and I think that that adds a whole other layer of complexity because until we start capturing that stuff for a while we're not even going to be able to report it because people aren't even entering that information into their electronic health record. So we should make a list from the 125 measures of all of the things that need to be in the systems or that people need to be documenting in order for those things to be reported out, but there's a ton of new things in there that call out new workflows, new capabilities, new fields in medical histories and all kinds of other things that we're not capturing regularly. That would be a good starting point before we start measuring it, is just to figure out what's not being captured that people have to start capturing.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

The questions in the NPRM reflect the questions that we've raised and it didn't get any easier, unfortunately, so David, I think we have to get on. We look forward to what the workgroup comes up with and we'll try to come up with some helpful comments back to –

David Lansky - Pacific Business Group on Health - President & CEO

Thank you all. It's very helpful.

Farzad Mostashari - National Coordinator for Health Information Technology

Thank you, David.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Larry, you asked for only 10 minutes, and the good news is you only have it. Thank you.

<u>Larry Wolf – Kindred Healthcare – Senior Consulting Architect</u>

The good news is I've had a chance to learn today from everybody and that's a great way to position what the Certification Adoption Workgroup has been asked to do and what we've already done. So we were asked to look at not the CMS rule on meaningful use but the ONC rule on standards. We got all our folks together and it was short notice and so we only had about half of them, but hopefully we'll get the rest on the follow up calls. Switching to the other NPRM, if you will, this is the one on standards implementation specification, certification criteria, etc., there are 8 things that we've pulled out of that to look at, and they range from the definition of certified EHR technology, this notion of a base with meaningful use core and meaningful use menu, safety enhanced design, user centered design, the reporting of errors, so we're running through the list, and then some specific areas that in the rule ONC asked for feedback on, so other healthcare settings, accounting of disclosures, disability status, data portability, and EHR technology price transparency. We got our charge, and I guess a subset, so for those who are into the details these are the areas in which ONC is asking for feedback on are these the right areas to actually apply user centered design, because they're the high priority safety areas.

We have a work plan. We had our first call, we reviewed the charter, and we demonstrated that we could easily dive into great depth without much – yes, it's going to be very hard to stay on track here. And then we broke up the work, of course three calls, so if anyone's interested in these topics here's the alignment of the topics to the calls. All of this stuff's published on the ONC Web site. Come join us on the virtual meeting. We'll be looking at, I expect the bulk of the time on the 9th will be on safety enhanced design. User centered design was an area we had some hearings on a couple of years ago. It's certainly a hot topic. ONC has worked on it, NIST has worked on it, IOM has worked on it, and we'll work through the rest of the schedule and have recommendations on comments back to the committee next meeting in May.

That's the plan. We'd really like to stay focused on the policy side of these and not get lost in the standards issues, because we know how easy it is for all of us to want to be standards experts when

we're not. We all have an opinion. So the opinion we want to have is around policy issues, so the workgroup tossed around some things that we thought would help us to stay focused on policy and so in terms of feedback I guess that's where I'd be looking to this group at this point for feedback. Are there things you think would help us stay focused on the policy side of the house or specific issues, sort of flipping back, so specific areas where it's a particularly policy sensitive area and we should be thinking this has got real implications, and even if it's not in the standard you should really be careful how you handle this one. So, any guidance or feedback for the workgroup?

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Good. Deven?

Deven McGraw - Center for Democracy & Technology - Director

It's a great list. Marc and I just had a side conversation about the accounting of disclosures. That would definitely be one that's policy sensitive. But it is one of those issues where there needs to be the sweet spot intersection between the technology and the policy, because it won't work without it. It's got to be an automated function in some way, shape, or form.

Larry Wolf - Kindred Healthcare - Senior Consulting Architect

Yes, like our measure discussion.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Yes, only this one feels like it might be easier, but I could be wrong. It's happened so often.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

All right, Christine?

Christine Bechtel - National Partnership for Women & Families - VP

One would be the piece I mentioned earlier about transport standards for Stage 1 if in fact we were to suggest that the care coordination criteria in Stage 1 no longer be the test, but was replaced with at least one successful transmission or something like that. The fact that there wasn't ... standards in Stage 1 is something that probably needs to be addressed, since people can start in that stage, as I mentioned, like in perpetuity. I think that's a gap area there and there are, I think two proposed in the Stage 2 rule.

Farzad Mostashari - National Coordinator for Health Information Technology

Just to clarify one thing, after 2014 and beyond every provider would need to use the 2014 edition certified products, so whether they're in Stage 1 or Stage 2 the products that they would have would be the 2014 edition, which would include all of the certification requirements.

Christine Bechtel - National Partnership for Women & Families - VP

Okay, so that makes a difference because trying to go and retrofit the Stage 1 stuff given development cycles you'd end up pretty much on the same timeline. Okay, that makes sense. The other thing that I would raise is there were questions in the NPRM around sexual orientation and gender identity standards, and in the work that we've done to look at this I do think we've got some more work to do there. But since you have ... disability status on the list it may be something that is worse looking at whether there are standards out there because I think there are a couple of health systems who have begun to do some work with it and I think there's some increasing amount of activity around the need to develop both the technical standards but also the workflows and tool kits that are similar to those that were done with race and ethnicity data. So I think the technical side of that might be something that you would consider here.

<u>Larry Wolf – Kindred Healthcare – Senior Consulting Architect</u>

Great. Any other comments, best wishes? Is anyone wanting to take leadership on one of those topics for us? Okay, thank you very much. We'll have a full report in less than a month.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Super, thank you very much, and thanks so much for another rigorous discussion. I can anticipate it will be as healthy, if not more, next month as we approach our final approval, so we'll plan to start at 9:00 next month. Why don't we open up for public comments then, please?

Mary Jo Deering – Office of the National Coordinator

Okay, operator, would you please open the lines for public comment?

Operator

(Instructions given.)

Mary Jo Deering - Office of the National Coordinator

We'll begin with people in the room. Please identify yourself before speaking. You have three minutes.

Tom Bizzaro – First DataBank – VP Health Policy & Industry Relations

I'm Tom Bizzaro with First DataBank and I would like to comment briefly on issues raised this morning by Dr. Tang about revision of drug-drug interaction rules. First DataBank has provided knowledge bases for clinical screening, including drug interactions, for about 25 years. Initially, those databases were used almost exclusively in pharmacies and pharmacy management systems, and in the last 10+ years that data has been used by many other healthcare professionals and what we have found is that there is a need for customization of those alerts depending on the expertise, practice setting, experience and patient information available to that healthcare practitioner. So I would endorse that suggestion that customization, which is a term we normally use for drug interaction rules, makes sense, as long as those rules are managed well and they're the result of some very thoughtful presentations. I thank the committee for the opportunity.

Carol Bickford - ANA - Senior Policy Fellow

Carol Bickford, American Nurses Association. When you come forward with the definition of the group measures it would be very helpful to clarify who constitutes the members of that group, because we have many advanced practice nurses and other clinicians in that space, so if you're getting value for eligible providers being physicians, then what happens to the members of the group that are not the physicians and you're looking about the team initiative, it becomes very important when you take a look at the group practices in the Medicaid space, that there's clear delineation of who those clinicians are. I'm also concerned about the movement forward on the measures that are being proposed because just counting them doesn't mean that you're making any quality initiative effective, that there's any change in the space. Just counting them doesn't mean that that's making a difference in my care.

Mary Jo Deering - Office of the National Coordinator

There are no more people in the room. Operator, do we have anyone on the line?

Operator

We do not have any comments at this time.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Thank you very much. I know that the workgroups will be busy, and go forth and be productive. Farzad has something.

Farzad Mostashari – National Coordinator for Health Information Technology

I wanted to correct something that I neglected to do in the beginning of the meeting, which was actually to introduce MacKenzie Robertson. MacKenzie, for those of you in the room, is sitting at the end of the table there, who is going to be our new Judy Sparrow and will be, over time, transitioning into the role of the Judy or the Mary Jo, who has really thrown herself into the breach, Mary Jo has, and has made it so that all of the important work of these federal advisory committees and workgroups went ahead really without skipping a beat. And I want to make sure we thank Mary Jo for once again her adding to her long and storied federal service in this capacity, and being such a critical part of the success that we've done in this really critical phase. So thank you, Mary Jo.

Mary Jo's going to stay the principal point of contact for a little while, while MacKenzie finds her feet, but I think you're going to find her to be a terrific person to take on this role. She's actually been the acting executive director of the National Biodefense Science Board, which is a federal advisory committee for the Assistant Secretary for Preparedness and Response, and prior to that was with ... and is very well versed in all the processes and requirements of the Federal Advisory Committee Act, so she's going to be a terrific asset for us, and welcome to MacKenzie.

Mary Jo Deering - Office of the National Coordinator

Excuse me, I understand we may have indeed one comment on the phone. They're often late coming in. Operator, do we indeed have someone on the phone?

Operator

Len Bowes, your line is live.

Len Bowes - Intermountain Healthcare - Physician and Senior Medical Informaticist

Hello. My name is Len Bowes from Intermountain Healthcare. Regarding the immunization registry issue that Marc Probst brought up earlier, I just wanted to get a little bit more detail. For some institutions, we, for example, use a Web tool that's provided by the state to enter our immunizations, and it is certified in our EHR but the data goes directly to the state and resides in their database. So we're required actually by the rules to, even though the data's at the state, we have to resend it again over an HL7 message, and I wanted to see if the group would consider an exemption for modules that have data that's already going to an immunization registry. That was just a follow up on Marc Probst's comments. Thank you.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

All right, we're adjourned and we will see you next month. Thanks.

Public Comment Received During the Meeting

- 1. June 04, 2012 At Hahnemann University Hospital in Philadelphia, PA we have been in a CPOE environment for over 20 years. Clinical Decision Support (CDS) is at the time of order entry. Workflow is key. The integration of CDS with workflow along with usability and business intelligence is where the creativity comes in building efficient and safe systems. Computer order entry is many times faster than using paper, in our setting; it is so much safer.
- 2. Communication with Patients: The problem for the provider is more than just whether broadband access exists in a geographic area. Even when infrastructure exists, even when there is measure of penetration that appears high, you have no way of knowing how likely it is that patients will be willing to communicate electronically. A physician in an area with good broadband, and 80% Internet use, may have a patient population that is mostly Medicaid and with high levels of ethnic and low socioeconomic groups that have no likelihood of electronic communication participation and the physician has no way of influencing this. And do not get fooled by reported Internet user penetration the standard measure is that a person who uses e-mail once a month (possibly in an Internet Café) is considered an online user. This means nothing when it comes to being able to establish electronic communication with a patient population. Making rules that assume the Internet is ubiquitous is not real.
- 3. Quality Measures: You will never catch up and never get anywhere if you focus on specific measures. What needs to be done is to use all the experience and intelligence available to design HOW to gather data and then HOW to use tools that can create a measure from that information. Then you can do the measurement whether it is for 1 measure or 1 million and whether you know what it is today, tomorrow or in the next century. You cannot hard code every measure for ever, so stop now and use the energy to get the system right.